Facing the consequences of the precautionary principle in European Community law

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This essay gauges the impact of the precautionary principle on Community decisions. To this end it reviews, first, judicial challenges of EC decisions accused of being insufficiently precautionary (“insufficient precaution” challenges), and, secondly, challenges arguing that the scrutinised decision is overly precautionary (“excessive precaution” challenges). The analysis indicates that it is prohibitively difficult for a private party to mount a successful “insufficient precaution” challenge. The positive trust-enhancing effect of the precautionary principle is negligible. The review of “excessive precaution” challenges illustrates the courts’ struggle simultaneously to validate broad discretion in decision-making and guarantee the substantive quality of precautionary decisions. The essay posits that current attempts to reconcile these two objectives create confusion, and may erode the credibility of decision-making. To avert this, and to strengthen the principle’s positive trust-enhancing effect, the Community must openly acknowledge the institutional empowerment that the precautionary principle entails, and devise a strategy to counterbalance it.

The precautionary principle, which posits that it may be warranted to undertake regulatory action to protect health or the environment in the absence of conclusive evidence of harm, is a central plank of Community policy, and a general principle of Community law. Since its adoption in the Maastricht Treaty on European Union, it has received ringing endorsements from the main Community institutions, it is an increasingly visible force in Member States’ law and policy, and it dominates the international debate on EU health and environment policy. Yet our understanding of the principle, and of its contributions to EC law, is itself plagued by uncertainty. This article aims to assess the impact of precaution as a legal principle, and to explore the reasons for the abiding confusion surrounding its importance. It will be argued that, thus far, the precautionary principle has not played a significant role in compelling decision-making by Community institutions. Its main function is to provide a rationale and justification for administrative discretion. However, to obtain a full picture of the principle’s role in EC law and grasp the root of the confusion, two additional factors need to be considered. First, in facilitating discretion, the precautionary principle confirms rather than alters pre-existing Community practice. Secondly, Community institutions, particularly the Commission and the European courts, struggle to reconcile the high level of discretion with a simultaneous desire to reassure the public about the quality and reliability of decision-making. The article argues that current attempts to reconcile these two objectives are unproductive, and will ultimately tarnish the credibility of the Community. To avert this, the EC must face the consequences of the precautionary principle, openly acknowledge the institutional empowerment it entails, and decide on more effective ways of counterbalancing it.

Introduction--a tale of success and scepticism

The history of the precautionary principle in the European Community reads as an unexpected success story. Inserted into the EC Treaty at Maastricht, its profile was overshadowed by the much more politically explosive Treaty innovations introduced at the time, such as the very concept of “European Union” and the codecision procedure. Moreover, the predictions for its impact were distinctly modest. By the late 1990s however, the principle gained momentum. The European Court of Justice (“ECJ”) discussed the precautionary principle in a couple of cases, and the notion of precaution in European (and national) law became a more frequently discussed issue in legal scholarship. This process accelerated dramatically in 2000, when the Commission released its Communication on the Precautionary Principle. The Communication, together with the political upheaval surrounding the trade conflict between the United States, Canada, and the European Union relating to beef hormones, during which the EU unsuccessfully tried to defend its ban on US and Canadian beef before the WTO Dispute Settlement Body by invoking, inter alia, the precautionary
principle, helped to turn precaution into the most prominent catchword in EC environmental studies, as the deluge of essays, articles, and books written on the subject since 2000 attest. Moreover, the principle has ripped through the confines of environmental protection, and established *E.L. Rev. 187* itself as a general principle of Community law. In the 2000 Communication, the Commission called the precautionary principle a “central plank” of Community policy, a sentiment echoed by the Court of First Instance (“CFI”) in the 2002 Alpharma decision. Two months later, in the Artegodan judgment, the CFI elevated the precautionary principle to a “general principle of Community law,” thus unequivocally confirming its legal significance, and the legitimacy of its application across policy sectors.

The Community institutions’ apparent enthusiasm for precaution is matched by a burgeoning scholarly interest. For instance, in “In the Union We Trust,” ECJ Judge Koen Lenaerts characterises the precautionary principle as a trust-enhancing principle of Community law, alongside the principles of transparency, equality of arms, and sound administration. Trust-enhancing principles, according to Lenaerts, aim to consolidate the trust which individuals should place in Union governance. They create trust because they compel Community authorities to make decisions in a responsible manner, and individuals can rely on the restraining power of these principles:

“administrations are no longer in a relationship of dominance vis-à-vis citizens, but they must make their behaviour conform to the principle of the sufficiently prudent and diligent ‘person’. A powerful expression of such ‘prudence’ at the policy level has consisted in the reliance on the precautionary principle, which the Court has backed and further organized in its case law.”

A different perspective emerges from Giandomenico Majone’s work. In “What Price Safety”, Majone alerts the reader to the principle’s “efficient aspect,” in which precautionary approaches tend to expand regulatory discretion at the national and international level. Majone observes that while discretion can serve legitimate public concerns, it can also facilitate protectionism, or result in fragmentation of global or regional public policy. Therefore, instead of enhancing trust, the precautionary principle may end up reinforcing the dominance of administrations over citizens, and thus erode the already precarious legitimacy of Community law. This concern is shared by a number of US commentators, who moreover warn that by slowing down innovation, the precautionary principle may well do more harm than good. While disagreeing on the nature and desirability of the changes wrought by precautionary principle, the above opinions clearly share the assumption that the principle has a significant impact on law and policy developments in the EU and beyond.

But not everyone is swayed by the alleged importance of the principle. In a 2003 publication, Noelle Eckley and Henrik Selin described the precautionary principle as “all talk and little action.” Karl-Heinz Ladeur referred to the way in which the precautionary principle has been used to inform EC decision-making under conditions of uncertainty as a “pyrrhic victory.” In “Guidance Without Constraint”, my analysis of the precautionary principle in the reform of EC chemicals policy supports the conclusion that its importance as a policy principle is easily overplayed, and that it is virtually impossible to identify policy initiatives that would not have been developed but for the precautionary principle.

The different views on whether the precautionary principle matters are at least partly fuelled by the inherent flexibility of the term. The precautionary principle can be invoked in a wide variety of circumstances, to justify an equally wide variety of actions. Precautionary action could refer to restrictions adopted where, for instance, the majority of the scientific community considers a particular product safe for consumption, but a minority opinion argues there could be some long-term risks in case of prolonged exposure. Or it could refer to action undertaken against activities that have been identified as potentially dangerous on the basis of a preliminary risk assessment, while awaiting the results of a more thorough, “fully quantified” risk assessment. Regulatory responses, in turn, range from direct bans or use restrictions, to much less forbidding requests for additional information on, say, the ecotoxicological properties of a new substance. If the EC’s precautionary action turns out to be predominantly of the latter variety (sometimes referred to as the “weak version” of precaution), it may well call the principle a “central plank” of Community law and policy, but one might wonder what all the fuss is about. The weak version of precaution is, after all, hardly distinguishable from the general preventative, risk-based principles for decision-making that have characterised Community policy since it first ventured into environmental, health and safety protection. If however the precautionary principle leads the Community regularly to adopt forceful regulatory measures in areas of high uncertainty (the “strong version” of precaution), the conclusions about its impact may be very different.
In sum, we are dealing with a principle that has received strong official endorsement, that is considered by some as a powerful tool to better the relations between administration and the citizens, by others as a potentially dangerous licence for arbitrary decisionmaking and protectionism, or as an irresponsible brake on innovation, and by still others as a tempest in a teacup. The following sections will examine EC case law pertaining to the precautionary principle in order to get a clearer picture on the role the principle has actually played thus far in Community decision-making, to assess its impact on EC law, and to shed further light on the question why, in its short history, the precautionary principle has been the subject of so many different characterisations and value judgements.

Examining the case law

Recalling the dual characterisation of the precautionary principle as a central plank of Community policy and a general principle of Community law, two avenues of investigation materialise. A first route would be to review the impact of the principle at the stage of policy and rule-making, analysing whether and how it influences and constrains EC policy makers. I have explored this question in a recent essay, concluding that the precautionary principle, while being a visible presence in EC health and environmental policy, has not compelled policy change. The present essay follows the second route of inquiry, analysing whether and how the precautionary principle is defined and interpreted in case law which reviews the binding acts that are the ultimate result of policy and rule-making.

The majority of case law involving the precautionary principle reviews the legality of binding Community instruments, issued either by the Council and European Parliament, by the Council or by the Commission, with reference to precautionary prescriptions. These tend to involve decisions on whether or not to include a particular substance, product, or process on a Community “positive list”, decisions on hazard classifications of substances and compounds, or decisions whether or not to authorise or renew an authorisation for the marketing of products that may pose health or environmental risks. Additionally, a few of the rulings falling within the first category review the validity of exemptions granted or withheld by the Commission to a Member State on the basis of Art.95(4) to (7) of the EC Treaty (“EC”), which allow Member States to impose more stringent health or environmental standards than the ones set out in harmonised Community legislation, provided a number of procedural and substantive criteria are met. In a second category of cases, the precautionary principle functions as a yardstick to review the legality of Member State rules implementing or derogating from Community obligations. Particularly in case law concerning free movement of goods, the Member States regularly use precautionary argumentation to justify national health or environmental regulations that suppress intra-Community trade.

This article focuses on the effect of the precautionary principle on decision-making at the EC level, rather than in the Member States. Hence, the reviewed case law concentrates on challenges to Community decisions.

The “insufficient precaution” challenges

At present, EC law counts seven cases where EC instruments were challenged for taking insufficient account of the precautionary principle, and one where a Member State invoked the insufficiently precautionary character of a Community act as a justification for its failure to comply with it. I refer to these as the “insufficient precaution” challenges.

In spite of there being a fair number, insufficient precaution challenges have thus far received little scholarly attention, the key reason being that “insufficient precaution” has rarely been the decisive ground for the Court to annul or confirm a Community act. Three cases failed for reasons of inadmissibility. The Art.226 EC infringement procedure was decided on grounds unrelated to the alleged insufficiently precautionary nature of the breached EC act. In a fifth insufficient precaution challenge, the claimant was successful in obtaining an annulment of the contentious Community act, but again for reasons unrelated to the precautionary principle. This leaves only three cases where arguments relating to the application of the precautionary principle played a decisive role: the Greenpeace ruling, the Codacons case, and Denmark v Commission. The two former complaints were dismissed; the latter signalled a first, modest victory for insufficient precaution challenges.

(a) Greenpeace and Codacons
The best known of the insufficient precaution challenges is undoubtedly the Greenpeace case, owing not least to the political sensitivity of area concerned, the regulation of genetically modified organisms (‘GMOs’).\(^{34}\) The French chapter of Greenpeace had mounted a challenge against a Decree authorising the marketing of genetically modified maize, taken in accordance with a Commission Decision ordering the French authorities to issue such authorisation.\(^{35}\) Greenpeace’s main argument before the Conseil d’État (‘E.L. Rev. 191\(^{36}\)) was that the Commission Decision and, consequently, the French Decree were adopted following an illegal procedure. In essence, the 1990 GMO Directive, which constituted the basis for the adoption of the Commission Decision, foresaw an authorisation mechanism whereby a Member State could initially decide freely whether to forward a technical dossier on a GMO intended for deliberate release to the Commission. But once the dossier was in the hands of the Commission, had been reviewed by the regulatory authorities of all other Member States, and had found approval, the initial Member State was bound by the Commission’s evaluation and could no longer retract its authorisation request.\(^{36}\) According to Greenpeace, such limitation of the Member State’s discretion was contrary to the precautionary principle. The Conseil d’État suspended the application of the Decree, and asked the ECJ whether the interpretation of the authorisation provisions in the GMO Directive, which resulted in tying the hands of the Member State once a GMO dossier had been forwarded to the Commission, was compatible with Community law, and particularly the precautionary principle.

In its reply, the ECJ pointed out that the requesting Member State did have an opportunity to assess the risks of the planned release prior to forwarding the dossier to the Commission, and that other Member States could comment on, and object to proposed authorisations during the review procedure. Moreover, the precautionary principle was adequately safeguarded in Art.16 of the Directive, which allowed Member States to withhold their consent if, in the mean time, new information emerged regarding the risks of the product.\(^{37}\) Thus, when confronted with the choice between securing internal market harmonisation and pushing the precautionary envelope, one could argue that the Court chose the former. However, Greenpeace’s argumentation was, in my view, insufficiently specific as to what possible health and environmental risks might not be sufficiently anticipated in the regulatory framework of the time, and one might reasonably question whether the precautionary principle was correctly invoked in the first place. The Conseil d’État’s willingness to suspend application of the contested Decree might say more about French political preferences, than the ECJ’s ruling says about its political agenda.

The precautionary principle was again raised in the context of Community GMO legislation in the recent Codacons case.\(^{38}\) The presence of GMOs must be indicated on the label of consumables, however exemptions are provided in the case of adventitious presence of GM material below a 1 per cent level. A question arose before the Italian court whether this exemption was also available for food products destined for infants and young children. EC law contains no provision on this specific issue, however the Italian consumer organisation Codacons argued that since EC law does contain other (non GMO-related) protective food safety rules for infants and young children, adherence to the precautionary principle warranted non-application of the exemption.\(^{39}\) The ECJ disagreed. Like the French Government in the Greenpeace case, Codacons did not enter into specifics on the scientific uncertainty surrounding the health effects of intake of *E.L. Rev. 192\(^{40}\) minimal quantities of GMO material by infants or young children, and this probably weakened its precautionary claims. In the absence of any sustained argumentation on the potential risks of applying the exemption, it is hardly surprising the Court chose not to validate a viewpoint that would have resulted in the judicial creation of a new rule on GMO labelling. Instead, the ECJ stuck to a more traditional pairing of arguments, stating that, first, in the absence of a lex specialis on the subject the general rules for exemption applied, and secondly, the Community authorisation, tracing and labelling rules for GMOs generally were sufficiently precautionary to meet the requirements of the eponymous principle.\(^{35}\)

(b) The Danish derogation: a modest victory for precaution

In Case C-3/00, the ECJ was called to review the validity of a Commission Decision that denied a Member State’s request for an opt-up from EC health and safety standards.\(^{41}\) In the wake of the adoption of Community standards restricting the use of sulphites, nitrates and nitrates as food additives, Denmark desired to maintain its pre-existing, stricter national standards. It submitted a request to the Commission following the procedure in Art.95(4) to (7) EC, which lays down the conditions under which Member States may derogate from harmonised Community requirements. After reviewing the Danish request, the Commission decided to reject it, observing that although the Danish measures were undeniably aimed at protecting public health, they were excessive (disproportionate) in relation to this aim.\(^{42}\) Denmark challenged the rejection before the ECJ. In a very
considered and balanced ruling, the ECJ sided with Denmark on the issue of nitrites and nitrates, but dismissed the remainder of the complaint pertaining to sulphites.

For the purposes of this essay, the salient elements of the Court ruling are the following. First, the Commission argued that the provisions in Art.95(4) to (7) EC did not intend to allow a Member State to substitute its own risk assessment for that carried out by the Community legislature. Hence, the Commission argued,

“(T)he fact that a Member State assesses a risk differently from the Community legislature does not constitute a ‘justification’ for maintaining derogating national provisions”.\(^{43}\)

This view is hard to reconcile with the respect for minority views in areas of scientific uncertainty, which the Commission itself has identified as a fundamental tenet of the precautionary principle on more than one occasion.\(^{44}\) It seems that, here, the Commission’s fears of the potential devolutionary effects of a broad application of the precautionary principle trump its desire for consistency. The Court, however, disagreed with the Commission and confirmed that:

“E.L. Rev. 193” \(^{(the)}\) the applicant Member State may, in order to justify maintaining such derogating national provisions, put forward the fact that its assessment of the risk to public health is different from that made by the Community legislature in the harmonisation measure. In the light of the uncertainty inherent in assessing the public health risks posed by, \textit{inter alia}, the use of food additives, divergent assessments of those risks can legitimately be made, without necessarily being based on new or different scientific evidence.”\(^{45}\)

The ECJ thus opened the door for differentiation in market regulation between the Member States on the basis of precautionary considerations, even in areas subject to harmonised Community standards. However, we should remember that the Court's view in this matter is restricted to situations where Member States seek to maintain pre-existing national regulations. The recognition of differences in risk assessment translates into a cap on new harmonisation initiatives, but does not cause previously harmonised areas to unravel, which would arguably be much more disruptive. For such an unravelling effect to take place, the Court would have to confirm—which it has not done so far—that differences in risk assessment constitute new scientific information on the basis of which a Member State may submit a request for the introduction of new measures deviating from the Community standards.\(^{46}\)

The second interesting aspect of the C-3/00 case relates to the issue of technological need. In its risk assessment for sulphites, which deviated from the Community assessment, Denmark had taken into account the reduced technological need for this substance. The Commission had reasoned in the contested Decision that whether the use of a substance was a technological necessity did not affect the likelihood that this substance would harm human health or the environment. Hence, the Danish risk assessment was misconceived. The ECJ however took a more contextual approach to risk, proffering that:

“technological need is closely related to the assessment of what is necessary in order to protect public health. In the absence of a technological need justifying the use of an additive, there is no reason to incur the potential health risk resulting from authorisation of the use of that additive.”\(^{47}\)

Yet ultimately this consideration bore little on the outcome since the ECJ decided that, even though the Commission Decision disputed the requirement to take into account technological need, it had in fact adequately considered technological need in its deliberations.\(^{48}\)

Finally, the ruling invites reflection on the role of scientific advice with regard to Community harmonisation measures. Denmark wanted to maintain stricter national standards for the use of nitrates and nitrites in foodstuffs, but the Commission considered the Danish rules excessively restrictive, and argued that the harmonised EC standards adequately protected human health. In the Court's decision on the issue, an opinion of the Scientific Committee for Foodstuffs ("SCF") played a pivotal role. In 1995, the SCF had issued an opinion on nitrates and nitrites, which specifically considered the provisions “E.L. Rev. 194” of Directive 95/2 on the subject. The opinion was critical of the Community standards, and noted that the residual amounts of nitrates permitted by Directive 95/2 were much higher than the levels justifiable on technological grounds.\(^{45}\) The ECJ considered the SCF observations relevant in assessing whether the Danish provisions were justified, and invalidated the Commission Decision that rejected the Danish request with regard to nitrates and nitrites because the Commission had failed to take into account the SCF opinion.\(^{49}\) This opens up interesting prospects for new uses for scientific advice, and may allow EC expert committees indirectly to influence public
policy via the route of national derogations, even if their advice is not or only partially followed at the EC level.

The failure of “insufficient precaution” challenges: incidental or systemic reasons?

So far, the Court has only once validated an insufficient precaution challenge, and has dismissed two. However, for reasons mentioned above, neither of the dismissed GMO cases constitutes a very strong or credible precaution-based challenge. Does this mean, then, that the waters for precautionary actions are largely untested? If anything, given the ECJ’s quite expansive interpretation of the precautionary principle in the Danish case, the prospects for precautionary challenges are arguably quite favourable. However, we should not forget that, first, Denmark was only partially successful and, secondly, the proceedings took place within the specific framework of a derogations procedure, which is deliberately designed to enable Member States to opt up from harmonisation measures. Moreover, additional factors should be taken into account, which suggest that the reasons for failure of the insufficient precaution challenges may not be purely incidental, but caused by more systemic obstacles.

Indeed, the dismissal of three claims on procedural grounds evokes the image of a legal system well stocked with procedural safeguards to defend binding Community acts against undesirable outside scrutiny. This is particularly the case when this scrutiny comes from a private party, as illustrated most emphatically in the Olivieri case. Here, a private claimant, Dr Olivieri, petitioned for the annulment of a Commission decision authorising the marketing of a new pharmaceutical. Dr Olivieri had been involved in the development and testing of a new drug for thalassemia major (Cooley’s syndrome), but withdrew from the process after data emerged indicating that the drug might not be effective, and might even create new health risks for the users. The main financial backer carried on, and requested the European Commission to authorise the drug for marketing. Dr Olivieri intervened in the authorisation process, submitting and documenting her opinion that the drug was not safe. The Commission reviewed her submission, but still decided to authorise the drug. The Olivieri case had great potential to break new ground: it concerned a positive request for precautionary action made by a private party who invoked the precautionary principle as a legal entitlement to public health protection; there was data indicating that the proposed authorisation might jeopardise human health, but there was scientific uncertainty, confirmed by an expert working group advising the Commission, which labelled the evidence as “inconclusive”. The CFI, however, dismissed the case after deciding Dr Olivieri did not have standing to sue. While acknowledging that she was entitled to ensure that the Commission examined the information she had submitted, the CFI decided that this right was exhausted at the moment when the information was examined and taken into account in the course of the assessment. The fact that Dr Olivieri’s contribution had not affected the outcome of the Commission’s deliberations did not change the Court’s assessment. Bearing in mind the close involvement of Dr Olivieri in the authorisation process, and her individual, specific interest in the subject-matter, the inadmissibility of her claim suggests that the chances for EU citizens generally directly to enforce the precautionary principle vis-à-vis Community administrations are as good as non-existent. The current standing rules constitute a prohibitive obstacle, and it remains to be seen whether future developments in this area will alter the scope for private challenges of Community acts in a significant way.

Even in cases where the claimant is a privileged applicant facing lower standing hurdles than an individual (say, a Member State), or if the validity of a Community act is raised indirectly via a preliminary reference, allegations of insufficient precaution will be hard to prove on the substance. There is the Danish case, but we must remember the specific context of the derogation procedure. Moreover, one swallow does not make a summer. Often, claimants will face a tricky situation where they need to prove that a particular risk is potentially serious enough that not acting on it constitutes a wrongful act of omission by the EC institutions. As there will necessarily be scientific uncertainty about the existence and imminence of the risk (for otherwise the matter would not come within the purview of the precautionary principle), that proof may be hard to find. Add to this the long-established EC judicial tradition of supporting administrative discretion in decisionmaking (further discussed below), and the fact that the Commission has underscored in its 2000 Communication that a precautionary decision may just as well be a decision not to act, and the odds for the claimants look bleak indeed.

In light of the absence of successful private challenges, and considering the many obstacles that darken the prospects for future success, Lenaerts’ portrayal of the precautionary principle as a trust-enhancing principle that will bridge the gap between the administration and the citizen appears
overly optimistic, possibly even misguided. Even if future developments will relax the conditions under which insufficient precaution challenges can be made, it is undeniable that, to date, the role of the precautionary principle as a legal tool to compel Community institutions to take protective action has been marginal.

“Excessive precaution” challenges

If, up to now, the precautionary principle has not been very useful as a sword to compel EC authorities into action, then maybe its impact lies in its power to shield Community decisions from outside attacks. To investigate this, we will review a number of cases where Community acts were challenged for being too precautionary (“excessive precaution” challenges).

*E.L. Rev. 196* (a) The antibiotics cases

Three of the most high-profile precautionary judgments to date are the Pfizer, Alpharma and Solvay decisions. The rulings, particularly the Pfizer and Alpharma ones, have been thoroughly scrutinised and discussed in earlier scholarship. It therefore suffices to recall the essentials, namely that each challenge contested a Council Regulation withdrawing a marketing authorisation for antibiotics used as additives to animal feedingstuffs. In each case the parties agreed that there was scientific uncertainty concerning the harmful effects of the antibiotics at the time of the Council Regulation. And in each of the cases, the CFI upheld the withdrawal, confirming that the Council had to be afforded discretion in decision-making, and that the Court would only check for manifest errors.

As much as for their outcomes, the rulings have raised interest because the Court seized the opportunity to formulate conditions of when and how precautionary actions can validly be taken. First, for precautionary action to be triggered, the perceived risk must be more than “purely hypothetical”. Even when no full risk assessment is available, action must still be based on “as thorough an assessment as possible”, and should only be taken when “sufficient scientific indications” support it. Opinions differ on the extent to which these requirements constrain regulatory action. In my view, the conditions structure the decision-making process, but hardly impose substantive constraints. The heavy reliance on relative terminology such as “purely,” “as (thorough) as possible” and “sufficient” leaves great flexibility for action, and the requirement for there to be some scientific input and some attempt at assessment constitutes a burden of production rather than a far more onerous burden of persuasion. They still accommodate action under conditions of what we might label pronounced uncertainty. The only truly substantive limitation of precautionary discretion can be found in the Solvay case. There, the Court declared that although recourse to the precautionary principle does not require a situation of urgency, the sheer structural similarity at the molecular level between the substance under review, and one concerning which more risk data is available, would not be enough to warrant regulatory action.

A second set of conditions relates to the circumstances under which precautionary actions can be decided in the absence of advice by the designated expert committee, or if the envisaged action goes against expert advice. The CFI decided that, in such cases, taking precautionary measures is only allowable in exceptional circumstances and if the scientific objectivity of the information used in decision-making is adequately guaranteed. As with the thresholds for precautionary action, the Court confirms discretionary authority, but attaches conditions. However, once again, it is questionable to what extent these conditions have real bite. The way they were applied by the CFI in Alpharma certainly gives pause. First, the CFI referred to the studies submitted in the course of the Council's review of the antibiotics marketing authorisation, particularly singling out a report produced by the World Health Organisation (“WHO”), and observed that it had no reason to doubt that those reports were drawn up based on the best available scientific data at the international level. It then succinctly continued that this also went for other, national reports submitted. This perfunctory assessment indicates that the Court assumes scientific objectivity unless clear counter-indications are present. This implies that, in the overwhelming majority of cases, meeting the first hurdle will be a formality. The CFI then investigated and dismissed a claim that the opinion of the Standing Committee, which must be consulted in the course of a withdrawal procedure, equated an opinion by an independent expert body, and immediately thereafter concluded that the absence of a scientific opinion did not invalidate the decision. The condition of exceptional circumstances that need to be fulfilled in addition to the guarantee of scientific objectivity, had apparently slipped through the mazes of the Court's attention. Thus, of the two conditions constraining decision-making in the absence of a scientific opinion, one was a formality and the second disappplied.
In sum, the antibiotics cases validated discretionary authority in cases of uncertainty, but simultaneously qualified it. The persistence of this pattern of “confirmation plus qualification” throughout the cases is quite remarkable; no statement is left unqualified. It seems the CFI wanted to take great care to dispel any appearance that, in validating the precautionary principle, it gave Community authorities a carte blanche. Whether the conditions are effective, however, is highly debatable.

(b) Monsanto

The Monsanto case was not a direct action for annulment, but a preliminary reference concerning the validity of a safeguard clause in EC law on novel foods, which Member States could invoke for health protection purposes. However, it is worthwhile to look at the ruling in this context, since it gives a good (and rare) indication of how, according to the ECJ, the precautionary principle affects the evidentiary thresholds for decisionmaking. The Court first lays down minimum requirements for intervention, stating that the safeguard clause may be invoked upon demonstration of a risk to public health, but that it may not be based “on a purely hypothetical approach to risk”. It continues that safeguard measures can be adopted only if they are based on a risk assessment which is "as complete as possible in the particular circumstances of an individual case". Member States satisfy the burden of proof if they have evidence indicating the existence of a “specific risk which those novel foods could involve”. Thus far the general requirements for action. However, the ECJ then goes on noting that “(in) addition”, the safeguard clause is an expression of the precautionary principle. Hence, protective measures may be taken even if it proves “impossible to carry out as full a risk assessment as possible”. Leaving aside the conundrum of how, logically, it could be impossible to do something as well as possible, the Court clearly seeks to validate a lowering of evidentiary standards as a consequence of the precautionary principle. However, it then continues that “(such) measures” (presumably safeguard measures taken in application of the precautionary principle) presuppose:

"that the risk assessment available to the national authorities provides specific evidence which, without precluding scientific uncertainty, makes it possible reasonably to conclude on the basis of the most reliable scientific evidence and the most recent results of international research that the implementation of those measures is necessary".

This last assurance seems to claw back most of the discretionary space just liberated by the precautionary principle, and thus, ultimately the clarifications in Monsanto create more confusion than they dispel.

(c) Artegodan

Structurally, the Artegodan judgment is quite similar to the antibiotics cases: it concerns a Community decision to withdraw a range of products (in this case anorectics or diet pills) from the market, which was based on incomplete evidence. There were no specific risk assessments for the anorectics under scrutiny; their withdrawal was mostly spurred by a strategic change in public policy, which now favours lifestyle changes over medicinal ways of combating obesity. However, Artegodan does differ from the antibiotics cases in at least two significant ways: the contested decisions were adopted by the Commission rather than the Council, and in Artegodan the CFI annulled rather than validated the market withdrawal.

For proponents of an expansive application of the precautionary principle, Artegodan is the best of cases and it is the worst of cases. On the one hand, it has spawned some of the most forceful endorsements the CFI has yet given to the principle. In addition to the previously mentioned “central plank” comment, the CFI referred to the precautionary principle as:

"requiring the competent authorities to take appropriate measures to prevent potential risks to public health, safety and the environment, by giving precedence to the E.L. Rev. 199 requirements related to the protection of those interests over economic interests." (Emphasis added).

The term “requiring” hints at the principle’s potential utility as a tool to compel Community action, even though, as we have seen, there has only been one instance of a plaintiff effectively using this tool so far. But on the other hand, Artegodan constitutes the first case where the CFI sided against the precautionary decision-maker. In a decision that goes back and forth between emphasising the high level of discretion afforded decision-makers in areas of high complexity, and repeating that the precautionary principle should not be an excuse for random decision-making, the CFI ultimately sided
with the plaintiff, concluding that there really was no new scientific evidence. There was only an alleged new consensus on the (lack of) benefits of diet pills—which moreover had been insufficiently documented by the Commission—and this not enough to justify the Commission's withdrawing of the anorectics in question.

(d) CEVA

The plaintiffs in CEVA complained of the Commission's failure to establish a maximum residue limit ("MRL") for a veterinary hormonal product, which rendered the company unable to market the product. Here, the Commission disregarded two consecutive opinions issued by the Committee for Veterinary Medicinal Products ("CVMP"), which advised to qualify a reviewed veterinary progesterone product as one for which no MRL needs to be established. The Commission did not pursue this suggestion, with the consequence that at the end of a transition period the hormone could no longer be marketed by CEVA. In its defence, the Commission argued that, in an area of Community law designed to protect human health, it would be illogical to suggest that it was obliged to follow one scientific opinion and disregard information from other reliable sources in its assessment of appropriate risk management measures. While acknowledging the advisory role of the CVMP, the Commission continued that the Committee's assessments are:

"balanced by the competent institutions against all the scientific information available, taking into account scientific uncertainty, consumers' concerns, ethical or moral considerations or other legitimate factors and the precautionary principle."

In its ruling, the CFI did not condemn the Commission's failure to act, however it did vindicate the applicants' claim for damages. The Court agreed with the Commission that the progesterone file was technically complex. However, given that the CVMP had confirmed its initial assessment of progesterone in a second opinion, reached after reviewing new scientific data presented to it by the Commission, the Commission could no longer reasonably disregard the legitimate interests of the applicants, who sought, at best, a confirmation that no MRL was required or, at least, the establishment of a provisional MRL, pending further investigations. Consequently, the CFI ruled the Commission's dismissal of the CVMP's opinions unlawful, and confirmed CEVA's entitlement to damages.

The complex lessons from excessive precaution challenges

The case law on excessive precaution challenges does not lend itself to straightforward conclusions. Going by the outcomes, there are thus far considerably more cases where excessive precaution challenges were dismissed, than where they were validated. This suggests that the precautionary principle can be an effective shield to protect Community acts from attack. Moreover, the factual background in Pfizer, Alpharma and Solvay, as well as the Court's attempt to distinguish "regular" from precautionary reliance on the safeguard clause in Monsanto, signal that the Court is willing to condone forceful measures taken under circumstances of pronounced uncertainty, in the face of contrary advice, or even in the absence of an expert opinion. All this suggests that the precautionary principle has an impact on Community law that is not only formally but also substantively significant. However, several additional considerations compel a more nuanced assessment.

First, it is questionable whether the high level of discretion in decision-making, which Majone rightly identified, is genuinely related to the introduction of the precautionary principle. Judicial deference to discretion in decision-making has been a staple of Community law since its inception. To preserve the robustness of Community law and regulation, the Court has always confined itself to marginal testing, only outlawing those decisions that were based on manifest errors of appreciation. The seminal Fedesa case is an early illustration of discretion at work in the context of scientific uncertainty. In Fedesa, the Court roundly confirmed that, in the absence of conclusive scientific data on the health impacts of a particular substance, the competent authorities should be left a wide berth of discretion to decide on the matter, and it was not for the Court to second-guess their assessment. A tradition of deference is equally well established in the assessment of regulatory interventions made by the Member State to avert uncertain threats. Hence, the precautionary principle is perhaps better qualified as a consolidation of pre-existing Community practice, than a new direction in EC law and rule-making.

"E.L. Rev. 201" Secondly, there are numerous indications that the Court is finding the task of verbalising and formalising the practice of allowing a high level of discretion in conditions of uncertainty rather trying. In its attempts to establish guidelines to distinguish acceptable from
unacceptable precautionary measures, the Court sometimes muddies the waters more than it clarifies. In Alpharma, the CFI introduces a standard of exceptional circumstances for decision-making in the absence of scientific advice, which it promptly fails to apply. In rulings such as Solvay, Artegodan and, most visibly, Monsanto, the CFI and ECJ repeatedly to-and-fro between confirming authorities’ competence to decide under conditions of uncertainty, and insisting that decisions should still be based on reasonably reliable information. It is admittedly possible to get a general sense of the direction the CFI and ECJ are trying to map out, but when attempting to apply these competing prescriptions in practice, we are hardly any wiser. In all but the most extreme cases (be it decisions taken in the absence of any hazard or risk information whatsoever, or decisions based on nearly complete information) it is impossible to predict whether the Court will ultimately attach more importance to its own dictates about allowing a broad discretionary margin, or its reassurances that there still must be “as reliable information as possible”. As long as we do not know which of the two tenets of its prescriptions carries the most weight, it remains difficult to confirm and predict the impact of the precautionary principle on Community law.

The different outcomes in two of the most recent cases, Artegodan and CEVA, are a third factor to consider. To some, Artegodan indicates that the Court is going for a more contained, perhaps weaker but more pragmatic interpretation of the precautionary principle. On the other hand, perhaps the factual background in both cases was genuinely much weaker than in the antibiotics cases. The crucial point is, due to the technicality of the files, it is virtually impossible for outsiders to form a reliable, independent opinion on the matter, and thus to interpret the significance of precaution in the Court’s rulings. Given all these complexities, the differing opinions and confusion about the impact of the precautionary principle on judicial review of Community acts is only to be expected.

The proof will be in the pudding. If, in spite of Artegodan and CEVA, the current trend of there being more excessive precaution challenges dismissed than validated continues, the position that the courts accept precautionary action under pronounced uncertainty, and therefore that the principle has a strong impact on Community decision-making, will become stronger and stronger. This would please proponents of the strong version of precaution. However, there is a price to pay. In a permissive climate, the Court’s repeated assurances that decisions should not be arbitrary, and should still rely on good science, may sound hollow, meaningless, even deceptive. A critique of this nature has already been made in the context of Pfizer; further cases may fuel greater concern. Ultimately, this development may tarnish the credibility of the precautionary principle as a sound principle for decision-making, and of EC decision-making processes as a whole.

On the other hand, Artegodan and CEVA may be the first in a new line of cases where excessive precaution challenges are validated more often than dismissed. This, in my view, is the more plausible development, since each new challenge of a precautionary decision offers a new invitation to the Court to specify and concretise the boundaries of precautionary action. Even when the decision under scrutiny does pass muster, the Court can give further indications on the kind of regulatory behaviour it would not find acceptable, as it did in Solvay. As information on the practical boundaries of precautionary action grows, the principle itself might transform from a facilitator to an evidentiary hurdle. If this happens, the outcomes of judicial review cases will become easier to predict, strengthening the legal certainty of the precautionary principle, and even bestowing a trust-enhancing quality, albeit of a negative variety in that the principle fosters trust in the citizens that the Community will not act unless certain conditions are met. However, its health and environmental impact on Community law would be stunted. In fact, recalling the Court’s history of condoning discretionary decision-making under uncertainty, the application of the precautionary principle might perversely result in the Court striking down more decisions than before the principle became a factor in decision-making.

Hence, in adjudicating excessive precaution challenges, the Court confronts two alternate challenges. If it emphasises the first discretionary tenet of the precautionary principle, it may stir up concerns about unbridled, arbitrary decision-making. If it focuses on the second tenet of sound science, it may end up stripping the principle of its impact on Community law.

**Facing the consequences of the precautionary principle**

The analysis of EC case law on the precautionary principle has uncovered a number of pressure points. Most importantly, the deck is stacked against “insufficient precaution” challenges. With only one successful challenge in the quite specific area of Art.95(4) to (7) EC derogations, and considering the obstacles private citizens face when trying to challenge the legality of Community acts, the positive trust-enhancing effect of the principle is negligible. Furthermore, when it comes to “excessive
precaution” cases, we see a Court struggling to come up with sufficiently concrete, logical and coherent prescriptions for precautionary action. Finally, the Court faces the daunting task of reconciling broad discretion with scientific quality assurances, without either undoing the purpose of the precautionary principle or turning the quality guarantees into as many empty promises.

How can these problems be managed? Can the European Community come up with a version of and mode of application for the precautionary principle that is both efficient and trust-enhancing? In my view, the solution certainly does not lie in repeated, sincere but ineffectual affirmations that, even when there is little reliable information, decisionmakers will use “the best information available”. Because no matter how adamantly such assurances are uttered, it is a defining feature of precautionary decisions that they are taken on a weaker evidentiary basis than other, “standard” decisions. Hence, they necessarily require a greater level of trust in the decision-maker than other decisions do. This, I believe, is the heart of the problem. Up to now, Community institutions have been reluctant to face the institutional consequences of precautionary decision-making. The 2000 Commission Communication, generally accepted as the most informative policy document on the application of the precautionary principle in the EC, explains the *E.L. Rev. 203* advantages of precautionary strategies from a health and environmental perspective, but is silent on why Community institutions are qualified to take precautionary decisions. ¹¹ No overt effort has been made to gain the citizens’ trust that the Council, the European Parliament, the Commission, or any other Community authority when it is involved in risk decision-making, will make appropriate decisions, even when they only have incomplete information available. Differently put, the desirability of a precautionary approach may have been sold more or less successfully to the European public, but the notion that Community institutions should be the ones deciding on precautionary action has not.

The missing institutional debate casts an interesting light on the courts’ tendency to launch into repeated confirmations of discretionary competence followed immediately by guarantees of expertise. It is obviously a dicey enterprise to step into the minds of the European courts, but it is plausible that the persistent pattern of “confirmation followed by immediate qualification” betrays a keen awareness of the high level of discretionary prowess that the precautionary principle bestows on EC decision-makers, and perhaps a concern on the part of the courts that these institutions do not have sufficient credibility to carry off this level of discretion. This concern then fuels a need for external factors to boost the credibility of decision-making, ending in the formulation of “good science”, or more precisely “as good as possible science”, caveats. This same concern about credibility might also be a factor in the CFI’s decision to validate the Council’s precautionary actions in the antibiotics cases, but to rule against the Commission in *Artegodan* and *CEVA*. The Commission, being neither directly elected nor indirectly representative of domestic democratic processes, is most dependent on expertise for its credibility as a decision-maker. ¹¹

Given the risks and limitations of boosting the credibility of precautionary decisionmakers through claims of expertise, the question emerges whether there are other paths towards this credibility, which might not only foster the efficient, but also the trust-enhancing aspect of the precautionary principle. A first and quite obvious strategy might be to argue that Community bodies have been taking precautionary decisions long before the introduction of the precautionary principle in the Treaty, and that therefore the principle could be viewed as an expression and consolidation of existing practices, rather than the start of a new one. The Commission had made statements in this vein, for example when it commented that the EC’s pesticides authorisation policy of 1991 was precautionary *avant la lettre*. ¹¹ Along the same lines, EC institutions might want to draw the public’s attention more generally to the experience they have in making decisions on the basis of incomplete information.

However, in the current Euro-sceptical climate, it would be foolhardy to assume that references to experience in decision-making will suffice to dispel legitimacy concerns. In fact, a “we have been doing it, and therefore we should be doing it” line of argumentation might cause more vexation than it quells. It therefore remains necessary to look for *E.L. Rev. 204* alternative ways to boost the credibility of EC institutions as precautionary decisionmakers. Two plausible avenues present themselves. The first is to strengthen the basis of precautionary decision-making through strict transparency and participation requirements. The Community is well aware of the virtues of openness in decision-making. The need for transparency is the subject of Declaration 17 to the Maastricht Treaty, and transparency and participation are two of the pivotal requirements for modern European governance as discussed in the 2001 White Paper on Governance. ¹² Since 2001, Regulation 1049/2001 requires EC institutions to give the public broad access to information. ¹¹ Moreover, in the environmental field, the EU has recently ratified the Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters. ¹² Existing
transparency and participation requirements also cover precautionary decisions, however the credibility deficit in the precautionary area raises the question whether, for this specific type of decisions, a higher level of safeguards should be introduced.

A second main course of action would be to reflect the uncertainty of the decision-making process in its output. Simply put, it is easier to accept a discretionary decision if it is readily reviewable. Greater openness to review could be fostered in two ways: by limiting the lifespan of precautionary decisions, or by relaxing the judicial hurdles to challenges of precautionary Community acts.

To put the above suggestions into effect, a useful first step would be to introduce a systematic requirement that, when a Community institution plans to take a decision in an area of risk regulation, it indicates whether this is a “standard” (i.e. based on what is conventionally considered a “full scientific risk assessment”) or a precautionary proposal. This could be an application of the giving reasons requirement enacted in Art.253 EC. In addition to fostering the production of information about the Community’s own understanding of what is in the precautionary zone of decision-making, the reasons requirement would give greater visibility to those deliberations that result in a decision not to intervene which, as the EC has been at pains to point out, is a plausible outcome of a precautionary decision-making process. Proposals for decisions within the precautionary zone could then be subjected to heightened public access requirements, either through more extensive public consultation provisions, or even through the adoption of genuine deliberative mechanisms of decision-making. At the output side, precautionary decisions could come with strict review requirements, or with a limited fixed lifetime. Moreover, when it comes to opportunities for judicial review, the Community should seriously ask itself whether the traditional standing requirements for non-privileged applicants, which have been so effective in insulating binding EC acts against attack, are appropriate for precautionary decisions. Given the ECJ’s well-documented reluctance to relax its interpretation of the standing rules for non-privileged applicants on its own initiative, this task would fall to the Member States, which could revise standing requirements via a Treaty amendment.

It would be naïve to assume that all the above suggestions can smoothly be transformed into law and judicial practice. Without question, implementation will uncover problems and complexities that will need to be confronted and managed. For example, the heightened procedural guarantees might cause the Commission, in its development of proposals for action, to either stay away from the precautionary zone, or to underestimate the uncertainty of planned risk decisions, and if so a response to either of these occurrences should be devised. Participation mechanisms unlock a host of challenges, ranging from identifying the public concerned to determining the appropriate role of different kinds of feedback. Also, a duty to review precautionary decisions after a set time raises the question of the decision-maker’s liability for previous, possibly erroneous, decisions. And undoubtedly, a review of standing rules will stir lively debates about how to broaden access in a rational way without creating a risk of inundating the already overloaded EC judicial system with frivolous litigation, and on how to avoid the creation of a new set of privileged applicants, determined no longer by legal status but by economic weight and superior organisation.

On the plus side, there could hardly be a better time for reform. Europe is presently the scene of both a vibrant dialogue on openness, and a burgeoning interest in precaution. As Margaret Shlesinger put it, we need only connect. The current Commission proposal for a Regulation to apply the Aarhus prescriptions to EC institutions and bodies covers both the openness and access to justice tenets of possible reforms. While its scope of environmental decision-making only partially overlaps with that of precautionary decision-making, it is an ideal starting point to ignite a structured debate on the institutional dimension of the precautionary principle.

Moreover, in light of the shortcomings of the current approach, it would be a regrettable mistake to dismiss the proposed changes offhand. They could boost the trust-enhancing role of the precautionary principle for the citizen, and supply an additional ground for legitimacy of Community decisions. This will make the European regulatory authorities and courts less exclusively dependent on claims to scientific expertise, which tend to be unconvincing and sometimes confusing under conditions of uncertainty. Considering the potential advantages, the Community would do well to face the consequences of the precautionary principle.

**Concluding remarks**

The precautionary principle has captured the people’s imagination to an unforeseen extent. If nothing else, it can be credited with reinvigorating the environmental debate in the third
millennium. In EC judicial decision-making, the principle's main function has been one of justification, attempted clarification and moderation of a long-standing tradition of judicial deference towards Community decision-makers operating in a context of scientific uncertainty. For a principle that has been hailed as much as it has been maligned for the controversial nature of its founding ideas, this is a surprisingly conservative outcome. Moreover, as the introduction of precautionary language pushes the courts to be more informative and explicit about discretion and its limits, thus far unaddressed questions of the credibility and legitimacy of the decision-maker rise to the surface. This article has argued that the Community's failure to confront the institutional dimension of the precautionary principle severely limits its potential as an efficient, and certainly as a trust-enhancing principle of EC law. In the current Euro-sceptical climate, mere months after the French and Dutch voted against the Constitutional Treaty, it is certainly a daunting task to focus public attention on the high level of European institutional empowerment that comes with a vigorous application of the precautionary principle. But at the same time, the Euro-constitutional crisis is a stark reminder that Community authorities cannot afford to ignore questions of legitimacy. From this viewpoint, the precautionary principle could play a new and exciting role as a catalyst to jumpstart the discussion on the extent to which the various Community institutions, in the first place the Council and the Commission, are trusted with making decisions under conditions of uncertainty, and about possible approaches to restore and bolster this trust.

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2. Joined Cases T-74/00, 76/00, 83/00, 84/00, 85/00, 132/00, 137/00 & 141/00, Artegodan GmbH v Commission [2002] E.C.R. II-4945, at [184].
4. The Maastricht Treaty was signed in 1992 and entered into effect in November 1993.
8. See fn.1 above.
11. Commission Communication, cited fn.1 above, paras 3 and 4 in fine ; and Alpharma Inc, cited fn.1 above, at [135].
12. Joined Cases T 74/00, 76/00, 83/00, 84/00, 85/00, 132/00, 137/00 & 141/00, Artegodan GmbH v Commission [2002] E.C.R. II-4945, at [184].
13. Since the precautionary principle falls within the European Community pillar of the European Union, and as both the Commission and Court have labelled it a principle of Community policy and law rather than Union policy and law, for the sake of consistency this article uses the terminology “Community institutions” when referring to European Union institutions as Community policy and law-makers.
15. ibid., at p.317.
16. ibid., at p.343.


21. Ladeur, cited fn.10 above.


24. Reflected in, for instance, the Resolution of the Council of the European Communities and of the representatives of the Governments of the Member States meeting within the Council of May 17, 1977 on the continuation and implementation of a European Community policy and action programme on the environment, [1977] O.J. C139/1.

25. See Veerle Heyvaert, cited fn.22 above.


34. Association Greenpeace France, cited fn.31 above.


38. Denmark v Commission, cited fn.33 above.


40. Denmark v Commission, cited fn.33 above.


42. Denmark v Commission, cited fn.33 above, at [63].

43. Art.95(5) EC.

44. Denmark v Commission, cited fn.33 above, at [82].

45. ibid., at [83].

46. ibid., at [109].

47. Ibid., at [113]-[114].

48. Olivier v Commission, cited fn.28 above.

49. Ibid., at [91]-[92].

50. See discussion at p.205, and fn.94 below.

51. See fn.1 above.


57. e.g. Solvay Pharmaceuticals, cited fn.55 above, at [125], [267]-[268], [282], [310].
58. ibid., at [129].
59. See, e.g. the assessments of Vos and de la Cruz Vilaça, cited fn.56 above.
60. Solvay Pharmaceuticals, cited fn.55 above, at [135].
61. Pfizer, ibid., at [141].
62. Alpharma Inc, cited fn.1 above, at [213].
63. ibid., at [222].
64. ibid., at [223].
65. ibid., at [227]-[240].
66. ibid., at [241].
67. Also observed by Ellen Vos, cited fn.56 above, at p.191.
69. ibid., at [105].
70. ibid., at [106].
71. ibid., at [107].
72. ibid., at [109].
73. ibid., at [112].
74. ibid., at [113].
75. Artegodan, cited fn.2 above.
76. ibid., at [183].
77. Denmark v Commission, cited fn.33 above.
78. It should however be noted that the case was decided on competence grounds rather than on the basis of the excessive precaution claim. Artegodan, cited fn.2 above, at [155].
80. ibid., at [63].
81. ibid., at [66].
85. See Julien Cazala, cited fn.56 above.
86. Ellen Vos, cited fn.56 above, at p.199.
87. See fn.1 above.
93. See fn.1 above.