The Dangers of too Much Precaution

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Hecate: ‘For you all know, security
Is mortals’ chiefest enemy’

One of the pleasures of being a member of the Edward professional family is the hospitality. As an intermittently hungry devil, I was treated to frequent, regular food in Heriot Row, a phenomenon whose human and material generosity seemed at the time merely delightful, but which now seems truly prodigious in light of my own experience of juggling the demands of parenthood, a busy practice and the other preoccupations of legal life. In honour of the many teas, lunches, dinners, whiskies and other organoleptic delights I have enjoyed over the years chez Edward, this article considers how lawyers, officials, government ministers and judges handle controversies about food safety. I wish to voice some doubts about the precautionary principle, and to submit that it is an imperfect basis for regulating controversies in a society dependent on technology and governed by law.

I enjoy cooking. If I could knowingly choose between cooking a piece of a chicken reared by a farmer who used no antibiotics in his feedstuffs, and a piece of chicken produced in a factory farm with no light, no freedom for the birds and no nourishment which I would naively regard as normal chickenfeed, I would choose the former. My choice would be guided by what I might call commonsense and instinct, not scientific knowledge. I would prefer ‘natural’ raw materials when cooking.

However, animals raised for food do not, in most European Member States, live a natural life. Their quarters are cramped and the farmers who rear them are short of money. The faster they put on weight, the better their health, the more quickly they can be sold. Feeding livestock is a technologically sophisticated activity. For years farmers in Europe (and elsewhere) have given their animals feed containing tiny quantities of antibiotic growth promoters to ensure they digest their food efficiently, avoid intestinal diseases and put on

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1 From Thomas Middleton’s additions to Shakespeare’s Macbeth.
2 A devil is the trainee of a ‘junior’ advocate at the Scots Bar.
3 One kilo of antibiotic is enough for 50,000 kilos of animal feed.
weight quickly. In 1968 a new antibiotic was identified in Belgium and named virginiamycin, after the American state where it was wrongly believed to have been previously identified. The substance turned out to be disappointing for treating human disease, since it was not soluble in water and could not be ‘delivered’ to sites of infection in the body. However, it was discovered to be a valuable contributor to the rearing of animals. Pigs which ate waste from the laboratory thrived (so I was told), as the antibiotic improved their digestion and reduced minor ailments which commonly affected livestock.

In 1970, nineteen antibiotic growth promoters, including virginiamycin and bacitracin zinc, were authorised for use as a feedstuff additive in farms in the European Community. The registrations of the two products were regularly updated and remained in force, with various adaptations, until they were banned by a Council Regulation\(^4\) whose legality was challenged before the Court of First Instance.\(^5\) The Court received lengthy and detailed written submissions on the law, and the facts, and the science. The oral argument lasted two days (ending after 10.00pm on the evening of the first day.) The Court’s judgment, issued on 11 September 2002, offered some language which offered general comfort for the industry, but also raised a number of troubling questions. I was one of the counsel involved in those cases. There was no appeal, and the litigation concerning the ban is now over. All antibiotic feed additives are now being phased out in Europe. The Belgian factory which makes virginiamycin has been sold by Pfizer Animal Health, and now supplies feed manufacturers outside the European Union. This article will reflect on some of the broader legal and regulatory questions presented.\(^6\)

1. THE VOCABULARY: RISKS, PREVENTION AND PRECAUTION

‘Words are the daughters of earth and . . . things are the sons of heaven’

Regulations govern many aspects of our lives: directly or indirectly, there are controls over the brakes on our cars, the wrapping of frozen food, the feed given to cattle, the polyurethane foam in household chairs. Some of these regulations stipulate standards to be adhered to by all products, other regulations permit the

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\(^6\) I express thanks to Professors Casewell, Majone, Joerges, Philips, Pugh and others who have attempted to instruct me in the relevant science and in risk management, and to Messrs. Gale-Batten, Killick and McCarthy with much appreciation for their contribution during the litigation.

\(^7\) Dr. Samuel Johnson, Dictionary.
sale of products only once they have been specifically tested and approved. Some chemicals and all pharmaceuticals are subject to especially stringent checks. Many standards are set at European level. The common market functions more easily if discrepancies in national standards for the same products are eliminated. It is politically and materially impossible for European Commission officials to decide these matters, so there are scores of Council working groups and committees which meet regularly, usually in Brussels, to consider the merits of new products, discuss controversial products, issue recommendations, or take decisions. Although they pursue consensus, these committees sometimes encounter disagreement along national lines (Belgium considers the product desirable, Finland considers it undesirable), or along technical lines (evidence convincing to Portuguese representatives, evidence unconvincing to Irish representatives). The manufacturer of a product or the national government to which it is most sympathetic may argue that the product is excellent and should be authorised for sale (or that its authorisation should remain valid). Critics may say the product should be banned or should not be authorised. A number of scientific committees exist to offer advice and technical guidance to the decision-makers. That advice is usually, but not always, accepted.

Committees, working groups and administrative hierarchies depend on words recorded in writing. Overly colourful use of words can significantly distort sober analysis. It is easy to say ‘safety first’, ‘take no risks’, ‘do not play roulette with human health’, and difficult to disagree with such sentiments. In ordinary speech, words like chance, odds, likelihood are often used casually, imprecisely. In the world of risk analysis, there is a special lexicon: risk, hazard, danger, threat, adverse outcome, uncertainty, proof, confidence, doubt, and even precaution, can each be used casually or precisely. A controversy arises. Is there a danger, a risk, a threat? How to analyse and how to decide? When looking at a supposed danger, gravity and probability should be separately considered. Risk is a combination of hazard and likelihood. If the hazard is not severe and the likelihood of occurrence is remote, the risk factor is low and acceptable; no action is needed. If the likelihood of occurrence is high, then action is appropriate, the more so if the event would be serious. If the event may be dire but the likelihood of occurrence is remote, action is unnecessary (an asteroid of one kilometre in diameter striking the Earth). These are easy challenges for the regulator. Unfortunately, debates about the precautionary principle usually involve a dire hazard and a hotly-debated likelihood. The proponent of ‘safety first’ calls for a prohibition on the ground that the worst might happen, the manufacturer says the fears are exaggerated, lobbyists of various hues opine vigorously, the public reads the newspapers and the authorities have to take a position.

‘Prévention routière’ is a common term for road safety policies in French-speaking countries. Prevention in this sense means the taking of measures to avoid already established dangers or lessen their frequency: speed limits, prohibitions on driving while intoxicated, hygiene requirements in restaurants and food factories.
Precaution means something different: the taking of action, always negative action, to prevent the possibility that harm may occur due to a threat whose nature and severity are not known. Precautionary policies bite before it is sure that action is necessary and, by definition, bite in the absence of proof. Thus precaution implies in this context the taking of legal or regulatory or policy steps to prevent the occurrence of a danger, even when it is not known that the danger will or can materialise. 8

2. THE RISKS WE RUN

King Richard: 'I have set my life upon a cast,  
And I will stand the hazard of the die.' 9

As ordinary citizens, we are irrational in our decision-making about the risks we are willing to run and those we consider it essential to avoid. The likelihood that a pedestrian who crosses the road when the traffic lights are against him will suffer harm thereby is considerably higher than the risk of contracting Creutzfeldt-Jakobs Disease (CJD) through eating contaminated meat: but we all do the former, and few of us would object to a ban on all meat as a way of reducing the risk of the latter. On 1 May 2003 the inhabitants of Beijing did not congregate to celebrate Labour Day; they stayed at home lest they catch SARS. Probably Beijing's smokers smoked as many cigarettes as usual on that day, and few Beijing inhabitants modified their behaviour to reduce the risk of contracting HIV/AIDS. Yet fewer than two thousand Chinese have died of SARS, while the country is the victim of an AIDS epidemic which has already killed thousands; and the incidence of smoking-induced diseases is rising rapidly throughout Asia. But a new disease with, as yet, no known remedy, is perceived as much more threatening than (or at least changes citizens' behaviour more than) a by now familiar disease with no known remedy, or an attractive habit whose danger has been known for some years. Thus the universe of citizens is not well-equipped to make these delicate choices and it makes them in a manner which is not logical.

An admirable book entitled 'Living with Risk' 10 explains the statistical likelihood of death while engaged in certain common activities such as playing

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9 Shakespeare: Richard III, Act V.

football, being a professional fisherman and being a miner. There is a 6,000 to one chance of dying in a car crash each year for a UK driver who covers an average mileage. This means 17 deaths per year among 100,000 people (or 170 deaths per year per million of the population). Playing football is less dangerous: 25,000 to 1 or 4 deaths per 100,000 each year. Non-smoking women under 35 who take the contraceptive pill face even better odds: 77,000 to 1, or 1.3 deaths per 100,000. Some will abstain even though they have 69,999 chances out of 70,000 of surviving. As we will see, it is difficult to decide wisely controversies where the statistical threat to the population is 1 per million or less. The threat is not non-existent, and the hazard may be horrid, yet the chances of harm materialising are far more remote than other harms to which society probably does not devote enough preventive effort.\footnote{There is a debate in the UK about whether it is preferable to spend millions of pounds on railway safety in order to reduce the odds of a small number of railway fatalities, whereas the same sum spent on road safety would save more lives.}

3. THE PRECAUTIONARY PRINCIPLE

*Our watchword is security*\footnote{Prime Minister William Pitt, the Elder.}

This brings us to the precautionary principle, which is an attempt to offer an intellectually and politically defensible framework for deciding controversies when the science is disputed. There seems to be no single authoritative version of the words which encapsulate it. Professor Per Sandin claims to be able to identify 19 versions.\footnote{P Sandin 'Dimensions of the Precautionary Principle' (1999) *Hum. & Ecological Risk Assessment* 889. See the many other sources (criminal, sociological, political) set forth in J Wiener 'Whose Precaution After All: A comment on the comparison and evolution of risk regulatory systems' (Special Issue 2003) *13 Duke Journal of Comparative and International Law* 202.} One of its precursors was the German notion of *Vorsorgung* or *Vorsorgeprinzip* (taking care in advance). It was referred to in international agreements on the environment such as the Rio Declaration\footnote{Declaration of 12 August 1992 on Environment and Development, following the United Nations Conference on Environment and Development held at Rio de Janeiro from 3 to 14 June 1992.} (which is in turn evoked in Article 1 of the Cartagena Protocol on Biosafety\footnote{‘In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.’}):

*In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.*
The Commission issued a Communication on the Use of the Precautionary Principle\textsuperscript{16} and justifies recourse to the precautionary principle where,

1. . . scientific evidence is insufficient, inconclusive or uncertain and there are indications through preliminary objective scientific evaluation that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the chosen level of protection.

Article 174(2) of the EC Treaty as amended mentions the precautionary principle as a doctrine relevant in the environmental field.\textsuperscript{17} The Commission has stated that the precautionary principle ‘has been progressively consolidated in international law and so it has since become a full-fledged and general principle of international law.’ Thus it seems clear enough that Community law and policy recognise and respect, even honour, the precautionary principle. Aware of the doubts relating to the principle’s possible abuse, when announcing the adoption of its Communication on 2 February 2000, the Commission said:

1. . . the precautionary principle is neither a politicisation of science or the acceptance of zero-risk but [that] it provides a basis for action when science is unable to give an answer. The Communication also makes it clear that determining what is an acceptable level of risk for the EU is a political responsibility. It provides a reasoned and structured framework for action in the face of scientific uncertainty and shows that the precautionary principle is not a justification for ignoring scientific evidence and taking protectionist decisions.\textsuperscript{18}

I will be submitting that these commendable sentiments have not been observed consistently in actual practice. The first thing to say is that the meaning of the principle is not precise.

1. Few legal concepts have achieved the notoriety of the precautionary principle. Praised by some, disparaged by others, the principle is deeply ambivalent and apparently infinitely malleable . . . an instrument of reconciliation between popular and expert government it becomes apparent that the principle may operate to conceal rather than resolve such tensions.\textsuperscript{19}

\textsuperscript{16} COM(2000) 1 Communication on the Use of the Precautionary Principle, 10.

\textsuperscript{17} ‘Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay.’

Certain formulations favoured by those who are sceptical about the use of technology would shift the burden of proof:

'...the applicant or proponent of an activity needs to demonstrate to the satisfaction of the public and the regulatory community that ... public health will be safe. The proof must shift to the party or entity that will benefit from the activity and is most likely to have the information.'

If 'safe' means 'guaranteed not to be in any circumstances unsafe', then this prescription is unrealistically severe, as cars, pharmaceuticals, vaccines and many other products bring dangers to health and safety as well as advantages. (Cheeses and alcohols bring pleasures as well as dangers.) If 'safe' means 'appropriately safe', then the principle is incapable of being disagreed with, but not very helpful for the resolution of specific controversies. Likewise, we are told that lack of full scientific certainty shall not be used as 'a reason for postponing measures to prevent environmental degradation'. Since scientific certainty is almost never present in any controversy, this formulation would justify measures everywhere or nowhere to prevent environmental degradation. The principle then is like a slogan, not an intelligible prescription for action.

European Institutions are not immune from extravagant formulations which cannot mean exactly what they say. In its Defence in the virginiamycin case noted above, the Council stated: 'the Community decided to withdraw the products until it can be demonstrated conclusively that they pose no present or future risks to human health.' The Council made a similar statement in its Observations in the Interim Measures proceedings. The Commission does not routinely advance such arguments: in the case of Nancy Olivieri v. Commission, an expert argued that the Commission had wrongly handled the process for authorising a medicine which she regarded as unsafe, and the Commission successfully defended itself at the interim measures stage. The President of the Court of First Instance stated in his Order:

'The Commission further points out that, in so far as no medicinal product is entirely without risk, the degree of acceptable risk will depend on the therapeutic value and uniqueness of the medicinal product in question.'

4. LOOKING AT THE BEST AND THE WORST

'Science is nothing but trained and organised common sense, differing from the latter only as a veteran may differ from a raw recruit.'

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This is one of many 'green' versions of the principle.
22 Ibid., Nancy Olivieri, para. 90.
23 TH Huxley.
A person without knowledge is likely to be ready to believe that each of two possible outcomes is equally probable. The more arcane the field of knowledge, the more difficult it is for the layman to make an intelligent or prudent decision as to an outcome’s likelihood. We are almost always uncertain about whether a supposed risk is real and how serious it is. Uncertainty may relate to cause, or to effect, or to both. Pitching a tent in Central Africa close to standing or slow-moving water is likely to lead to mosquito bites and, unless the camper has been taking a prophylactic anti-malaria medicine, there is a measurable risk of being infected by a serious blood-borne malady. There may be uncertainty as to effect: does extensive use of a mobile telephone increase the incidence of brain tumours? There may be uncertainty as to both, as in the case of a medicine which is said to be statistically associated with certain health problems.

The best approach for rational decision-making is to look at all possible outcomes, not only the worst outcome, and to consider the likely consequence of action, including the risks associated with a prohibition. The entire problem should be examined taking into account every available piece of information. This should involve considering all probable events, all available regulatory decisions, and all the combinations of decisions and events which might occur. Moreover, the decisions should be capable of being rationally up-dated from time to time.

Read calmly, the foregoing ideas are likely not to be very controversial. How we apply the doctrine in disputes is controversial: however, encouraging prohibition in the presence of doubt implies either that huge numbers of products which are not acceptably unsafe would be banned; or that the selected few unlucky products would be chosen for prohibition in an arbitrary and unpredictable manner.

The precautionary principle preaches that where scientific knowledge is ‘insufficient, inconclusive or uncertain’, society may properly act conservatively to eliminate the ‘danger’ provisionally; whereas if scientific knowledge were complete, a formal risk assessment could be completed and an informed decision taken definitively. But real life does not correspond to these chosen alternatives: the normal condition of the well-informed expert is to be neither perfectly knowledgeable nor perfectly ignorant. The normal condition is to have some data about which not all experts will agree. If the level of knowledge is characterised as imperfect, the precautionary principle may be applied and it will be legitimate to be ‘tough’, cautious, conservative, risk-averse, protective of public health, and so on. In this climate, it will seem reasonable to ban the product until matters become clearer. A ban in such circumstances will be based on the assertion that knowledge is ‘inadequate’, when that inadequacy may reflect an ideological debate rather than an incomplete picture. Worse, perfect know-

24 The molecules fenfluramine and dexfenfluramine, anti-obesity medicines developed by Les Laboratoires Servier, have been the subject of over 6,000 articles in medical literature, and are probably the most copiously examined and commented pharmaceuticals in history, yet there is still controversy about their risk/benefit ratio.
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ledge is virtually unattainable (and only a fool would believe he had attained it). This means that for many, many products it will be impossible to show that there are no risks; *ergo*, knowledge is not adequate; *ergo*, a ban might be reasonable. The ban may be described as provisional, but in many cases its application will be permanent. A product once prohibited can hardly ever be rehabilitated.

5. TWO EXAMPLES OF POSSIBLY EXCESSIVE CAUTION

The precautionary principle has the potential to open the field to decisions driven by discretionary caprice. I offer two amateur doubts about the dangers of well-intentioned regulation.

Justified by reducing the danger of liver cancer, from which 35,000 Europeans die each year, a ban was proposed on nuts and grains from a number of African countries, for fear that they might contain aflotoxins which could involve a risk of 1.4 deaths per billion, or one life every two years in the European continent (a billion is one second in 37 years). The likely cost was estimated at 670,000,000 dollars, and endangered the livelihood of hundreds of thousands of African farmers.

A second example is the pesticide DDT which has been largely eliminated as a chemical in most countries because of its effect on the reproductive process of birds of prey. DDT was extremely successful in controlling the mosquitoes which carry the malaria parasite. In countries where malaria was endemic, spraying was a cheap and effective means of suppressing the danger. Donor countries frown on the use of DDT, and poor countries have tried to suppress its use. Cases of malaria are rising: there were over 300 million last year, and a million deaths. As DDT has been phased out, the great strides in controlling malaria in the 1940s, 1950s and 1960s have been reversed. There is a fiercely debated literature, and I have no conclusion to offer, but I submit that the matter deserves to be considered calmly.

6. THE RESOLUTION OF DISPUTES

'*... where ignorant armies clash by night'*

Scientific method typically involves the advancing of several different theories, followed by a cautious adaptation of those theories in light of greater knowledge.

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27 Matthew Arnold: *Dover Beach*. 
The incorporation of new evidence and new data which is processed intelligently should normally lead to convergence of opinions. Science is a discipline which pursues unanimity in the form of concepts, laws, and principles which are agreed and accepted as axioms upon which subsequent scientific research is built. The notion of public knowledge connotes the emergence of doctrines and theories which are the best reconciliation of diverging opinions which scientific method can deliver on the basis of available data. But some of these axioms are not yet capable of being demonstrated as universally valid under laboratory conditions. If uncertainty’s presence justifies a departure from normal scientific method, we will rarely follow scientific method. It is regrettable that when confronting diversity of opinion, the process of decision-making, both at institutional level and before the European Courts, changes (even degenerates?) from the characteristic of academic scientific debate which involves the pursuit of convergence between different observers of known phenomena. It becomes a process of advocacy, in which the scientist is deployed as an advocate propounding the rightness of one approach or the other approach.

During the debate about the use of antibiotic growth promoters in European farming, Scandinavian government officials took the position that as a matter of high policy, such products are undesirable, potentially harmful and deserving of prohibition. On the other side were scientists asserting that the risks were hypothetical, that a full risk analysis should be made, that ongoing enquiries would reveal useful information, that there was not no risk, but that such risk was rather trivial and that the evidence advanced (by Denmark, whose national ban triggered the subsequent Council ban) did not reveal any emergency justifying the prohibition of a product. Each side was in good faith. Each side had defensible scientific arguments to deploy. The European Court of First Instance in Cases T-13/99 (Pfizer Animal Health: virginiamycin) and T-70/99 (Alpharma: bacitracin zinc) was confronted with two groups of learned professors of medicine. Each sounded convincing, and each endorsed one side of the debate. They spoke partly as expert witnesses and partly, in a sense, as advocates for one view or the other.

Unfortunately, the Court did not take the preliminary step of inviting the experts of each side to sit together and produce a common document recording the points as to which they agreed and the points as to which they disagreed. Nor was the Court able to benefit from the proper testing of one expert’s theories by questioning from counsel educated by another expert.28 The legal submissions therefore tended, on the one side, to emphasise grave danger (‘bodies in the streets’, ‘nightmare reality’, ‘ultimate spectre’, and the need to ‘run no risk with public safety’), whereas on the other side the manufacturers emphasised the need for further enquiry, due process, the exhaustive enquiries and checks already carried out, 30 years of trouble-free use, and similar notions.

28 The Court’s tradition does not lend itself to, but I would submit the Court’s rules do not preclude, such a mode of enquiry.
The process of litigation does not enhance the likelihood of scientific consensus: to the contrary, it can make scientists into advocates arguing that their side is right and the other side is wrong, whereas if the scientists had been invited to do so they could have produced a helpful explanation of where they disagreed, how significant was that disagreement, and might also have been able to reach consensus on statistical probabilities.

7. THE US JUDICIAL EXPERIENCE OF SCIENTIFIC CONTROVERSIES

'Perfect safety is a chimera; regulation must not strangle human activity in the search for the impossible'\(^{29}\)

In the United States there have been a number of judgments of superior courts concerning scientific controversies. Two strands seem noteworthy, both pertaining to scientific rigour, one as to minority scientific theories, and the other as to standard-setting. The US litigation system creates huge economic incentives for lawyers and their clients to win cases where damage awards are pronounced by juries of laymen. The role of the expert scientist as a paralegal litigation asset has given rise to an extensive literature and numerous attempts, sometimes successful, to invoke before American courts the so-called Daubert Principle to prevent juries being confused by scientific opinion which lies very much in the minority.

In *Daubert v. Merrell Dow Pharmaceuticals*,\(^{30}\) the Supreme Court confirmed that a trial judge was under a duty to ensure that scientific testimony was not just relevant to the controversy, but also reliable enough to be advanced to the jury. Among the factors to be considered in examining whether proffered testimony is 'junk science'\(^{31}\) are whether the theory can be tested or demonstrated, whether it has been subject to peer review and publication, whether it seems to be prone to errors and exceptions, and its general acceptance by the scientific community. In *Kumho Tire Co v. Carmichael*,\(^{32}\) the court extended the Daubert 'gatekeeping' constraint to include a prior check upon all expert testimony, whether from scientists or those who claim technical or practical experience (in that case, the excluded testimony came from a man who could identify why tyres had failed by looking at their physical characteristics). Thus, the Supreme Court stated that it was legitimate for a trial judge to decline to allow the advancing of 'scientific evidence' which did not correspond to recognised scientific doctrines.

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\(^{31}\) A contemptuous term commonly used by those who defend companies against claims based on novel technical theories.

Thus the US courts have endorsed the principle that scientific input should be in the mainstream of opinion in order to be cognisable during the course of a trial. By contrast, the European Court of First Instance has stated that the Institutions were entitled to rely on a minority opinion, although that opinion should not be fanciful or hypothetical. We will also note below various WTO controversies in which world trade bodies have favoured a more robust standard of confidence based upon mainstream scientific opinion.

It is equally interesting to note how the US courts have dealt with the setting of standards of exposure. In such early cases as *Tennessee Valley Authority v. Hill*, the Supreme Court reluctantly endorsed the taking of action in precautionary circumstances at a time when there was acute anxiety in the US about degradation of the environment. It sharply reversed direction in the *Benzene* case noted above, where it chastised the agency for setting the standard for the presence of a dangerous contaminant by reference to mere conjecture about possible risks. The Occupational Health and Safety Administration had set 1 part per million (1ppm) as the acceptable maximum exposure of workers to benzene. There was of course no certainty as to what would be a safe standard, but on the other hand there had been no quantification of the number of illnesses which would have been prevented by the new standard. The agency felt that the appropriate threshold for carcinogens ought to be the lowest feasible level of exposure. The agency should have shown there was 'significant risk', and the Court noted that 'safe' is not the same as 'risk-free'.

On the basis of conversations with various specialists and experts, I have the impression that US regulation today corresponds more closely to mainstream scientific opinion, whereas European regulation is more unpredictable once

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33 437 US 153 (1978): This was the celebrated *Snail Darter* case, where the construction of a dam on the Little Tennessee River was halted for fear of damaging the habitat of a population of snail darter fish (which subsequently have been found to thrive elsewhere), there being 90 other species of darter fish in the State of Tennessee. 'It may seem curious to some that the survival of a relatively small number of three-inch fish among all the countless millions of species extinct would require the permanent halting of a virtually completed dam for which Congress has expended more than $100 million. The paradox is not minimized by the fact that Congress continued to appropriate large sums of public money for the project, even after congressional Appropriations Committees were apprised of its apparent impact upon the survival of the snail darter. We conclude, however, that the explicit provisions of the Endangered Species Act require precisely that result.' (p. 172) See also Justice Powell's dissent: 'Here the District Court recognized that Congress, when it enacted the Endangered Species Act, made the preservation of the habitat of the snail darter an important public concern. But it concluded that this interest on one side of the balance was more than outweighed by other equally significant factors.' (p. 213).

34 'These assumptions are not a proper substitute for the findings of a significant risk of harm required by the Act.' (Benzene, above n 29, at p. 662). Likewise, 'When the administrative record reveals only scant or minimal risk of material health impairment, responsible administration calls for avoidance of extravagant, comprehensive regulation.' (Benzene, p. 664).

35 One part per million is 1 inch in 16 miles, 1 centimetre in 10 kilometres.

36 Above n 29, Benzene, p. 655.

37 Above n 29, Benzene, p. 642.

38 There was an interesting discussion of these questions at the European Policy Centre's conference on 'The US, Europe, Precaution And Risk Management,' 19–21 June 2003, Berlin, when
controversies arise. This seems particularly true with respect to procedure, methodology and judicial review. However, as to the substance of what is being guarded against, the picture is not consistent.

The admirable article by Jonathan Wiener\(^3\) mentioned earlier shows that the United States is sometimes very cautious, even precautionary, sometimes not; and that Europe and North America do not always agree as to what they should be worrying about. Wiener notes that the United States severely limits the use of diesel engines in passenger cars in order to reduce suspended particulate matter from exhaust emissions, whereas Europe promotes diesel engines to reduce CO\(_2\) emissions. Both sides of the Atlantic are acting to protect the environment, but they are doing so in a very different manner. Likewise, various public authorities in the United States have imposed severe restrictions on the donation of blood there by those who have been living in Europe, for fear that European residents who offer blood may have contracted variant CJD due to eating beef products contaminated by Bovine Spongiform Encephalopathy (BSE). New York bans European blood donors even though no one has yet been shown to have contracted CJD via a blood transfusion. In Europe, the consequences of refusing blood donations from all European residents for fear of CJD infection would, naturally, be regarded as excessively severe by comparison to the modest public health advantage. However, some 200 articles confirm that the hazard is not hypothetical.\(^4\)

8. CONSTITUTIONAL PROBLEMS

A further reason for an EC lawyer to be uneasy about the precautionary principle is constitutional, both internal and external.

The internal dimension

There is often a spectrum of opinion, extending from passionate zealotry at one extremity to true scientific confidence (as taught in high school chemistry lessons) at the other. Official policy is made by individuals whose collective sentiment is likely to lie between these poles. There is rarely no evidence which the zealot can deploy, and very few scientists can be totally confident about safety specialists in various disciplines compared and contrasted approaches in very diverse areas (environment, penology, food standards, and even foreign policy).

\(^3\) J Wiener, above n 13.

in every circumstance. We will now note how the European Court has dealt with such controversies, where one Member State sees danger and another Member State (or the Commission, or a citizen) sees a hindrance to freedom.

The European Court of Justice and the Commission used to be confronted repeatedly with justifications offered by Member States for maintaining national standards on flimsy grounds of public health. Blackcurrant liqueur, blood sausages and beer were only some of the many cases. In some, the European Court looked at the specific facts and circumstances and was able to reject the national arguments as unfounded. Indeed, it is not difficult to mock the suggestion that German beer as liquid bread is important to the health of the labour force. However, not every case was easy. In the Nisin case, the European Court was confronted with a cheese additive: some countries banned it, some did not. Opinions varied. The Court declined to interfere with the application of a national prohibition on the use of the product. In other cases where the concern about public health appeared genuine, even if Member States' opinions varied, the Court was willing to uphold the prohibition. See, for example, Mirepoix and Melkunie, both concerning safety levels of extraneous matter in food.

On the other hand, in Commission v France, the Court rejected French essentially precautionary arguments against allowing the sale in France of British beef after the winding down of the BSE crisis. This is to be contrasted with the Court's rejection of appeals by the UK meat industry against a ban which addressed anxiety about BSE. Nevertheless, in Denmark v. Commission, the Court held that a Member State is entitled to decline to follow Community harmonisation legislation on the grounds that the risk to public health appears to be more severe than contemplated when the harmonisation measure was adopted. Denmark lost a Council vote in 1995 on certain food additives, and in 1999 informed the Commission that it proposed not to respect the standards adopted, and requested the Commission's approval. The Commission refused the request on the grounds that Denmark’s measures were disproportionately burdensome, having regard to the needs of public health. Denmark challenged that decision, successfully, before the European Court of Justice. The Court found that:

"... 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

41 170 pages of Peter Oliver's Free Movement of Goods in the European Community (Sweet & Maxwell, 4th ed, 2003) are devoted to cases involving justifications based on Article 30 of the EC Treaty.
42 Case 17/84 Commission v Germany (beer) [1987] ECR 1227.
45 Case 97/83 Criminal proceedings against CMC Melkunie BV [1984] ECR 2367.
48 Case 3/00 Denmark v. Commission (judgment of 20 March 2003, not yet reported)
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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, 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.

A Member State may base an application to maintain its already existing national provisions on an assessment of the risk to public health different from that accepted by the Community legislature when it adopted the harmonisation measure from which the national provisions derogate...«49

As to sulphites, the Commission's decision survived scrutiny, but as to nitrites and nitrates, the decision was annulled. There are genuine differences of policy and opinion between experts and between governments: the Danish Nitrite judgment suggests that Member States on the losing side in Council votes where public health questions are genuinely debated may disregard the Community norm and retain a national standard, even if this standard is based on opinions outwith the scientific mainstream.

It is very difficult to reconcile the mass of European Court judgments which confront the challenge to a common market of sincerely held opposing national opinions. There are many cases, and with ingenuity they can be fitted into a coherent mass,60 any imperfections in which are made more palatable by the popularly recognised importance of the Court's role as a reconciler of contradictory European and national values. Scientific rigour was given less importance than the constitutional goal of building a rationale which favoured free movement while not dishonouring local preoccupations.

Many of the difficult cases did not involve great sums of money or big constitutional principles. The Court gave an answer (sometimes it changed course) and life moved on. But the external environment seems less forgiving. More harsh in analysing science, less courteous in respecting national anxieties.

9. THE EXTERNAL DIMENSION

Hamlet: 'We defy augury'61

There are many situations where countries in the world trading system have elected to exclude or limit other countries' goods on the grounds of public health. WTO members are not compelled to align their domestic policies, but they are compelled to act in a transparent and non-discriminatory manner in

49 Ibid., paras 63 and 64.
60 Roman lawyers are familiar with the efforts of mediaeval glossators who devoted huge creativity and diligence to reconciling inconsistencies in Justinian's Digest, a work even longer than the Bible: perhaps future generations will look similarly at the first forty years of the European Court's jurisprudence on free movement of goods.
61 Shakespeare, Hamlet, Act V.
their treatment of foreign goods as compared to domestic goods. What level of scientific confidence is necessary in order to exclude, on grounds of public health or the environment, products which are unwelcome as a matter of domestic policy?

Hormones have been controversial both internally and externally. A 1985 Directive prohibiting the use of hormones in the rearing of food animals was challenged by the UK as having been brought under the wrong legal basis, and as being based on flawed science. The UK noted that the official scientific experts of the Institutions had not endorsed a ban. Further consultations of these experts were discontinued and the rationale moved—genuinely—from the confident ground of public health to the slippery one of consumer interest. A measure which was originally criticised by mainstream scientific opinion survived challenge in Luxembourg when re-branded as a measure which corresponded to the widespread will of the population.\footnote{Case 68/86 United Kingdom v. Council [1988] ECR 855.}

However, the measure did not survive challenge under the WTO rules. In \textit{Hormones},\footnote{European Communities-Measures Concerning Meat and Meat Products (Hormones), Report of the Appellate Body, WT/DS25/AB/R (16 January 1998).} the Appellate Body stated that it was not enough to rely on an ‘identifiable risk’ since ‘science can never provide absolute certainty that a given substance will not ever have adverse health effects’. The \textit{Hormones} Panel Report was polite but sceptical about whether a ‘risk assessment’ occurred: ‘an assessment of risk is, at least for risks to human life or health, a scientific examination of data and factual studies; it is not a policy exercise involving social value judgments made by political bodies.’\footnote{European Communities-Measures Concerning Meat and Meat Products (Hormones), Complaint by the United States, Report of the Panel, WT/DS26/R/USA (18 August 1997), §89.} The evidence was too general and non-specific to justify a ban. After a risk assessment has been carried through, WTO members can choose their appropriate level of sanitary or phytosanitary protection.\footnote{The Panel Report does not acknowledge the fact that ‘appropriate level of sanitary or phytosanitary protection’ had already been interpreted in Annex A in a way that essentially condones regulatory diversity.} There are several Panel Reports along similar lines. The \textit{Salmon}\footnote{Australia-Measures Affecting Importation of Salmon, Report of the Appellate Body, WT/DS18/AB/R (20 October 1998), 123.} Appellate Body report confirmed that it is ‘not sufficient that a risk assessment conclude that there is a possibility of entry, establishment or spread of diseases and associated biological and economic consequences.’

In a very recent case about apples from the United States the Panel found that Japan had gone too far in limiting apple imports to avoid the danger of fire blight.\footnote{Japan-Measures Affecting the Importation of Apples, Report of the Panel, WT/DS245/R (15 July 2003).} In violation of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures, the Japanese measure was ‘maintained without sufficient scientific evidence’ and was not ‘based on’ a risk assessment. The Agreement says that where ‘relevant scientific evidence is insufficient’, a
Member may ‘provisionally adopt’ measures on the basis of ‘available pertinent information’, provided that it seeks to obtain ‘the additional information necessary for a more objective assessment of risk’ and reviews the measure within a reasonable period of time. The ‘additional information’ which Japan had gathered demonstrated why the measure was not necessary in the first place: there was already in existence a large amount of scientific evidence demonstrating that the risk of transmission of fire blight through apples was negligible.

The Japanese risk assessment was conducted on the basis of a ‘general assessment’ of possibilities of introduction of fire blight into Japan through a variety of routes, including—but not limited exclusively to—apples. It was ‘not sufficiently specific to the matter at issue to constitute a proper risk assessment’. 58

In each of these cases, we can see strongly-held sentiments coming to grief in the absence of rigorous scientific support. 59 An even bigger controversy looms. On 13 May 2003 the United States formally initiated its complaint against the EU moratorium on granting approvals for new agricultural products created via biotechnology. Several Member States have imposed bans on the planting or sale of GMO (genetically modified organisms) crops, and these bans have not been challenged by the European Commission. A significant percentage of consumers in Europe believe GM foods are unsafe, or less safe than conventional foods (how different GM foods are from others, and indeed what is and is not a GM food, are each indeed a topic of debate). Once again, we see passion and some science on one side of the debate, reassurances on the other side, and a doubtful public.

Bio-tech producing countries argue that the moratorium violates WTO disciplines prohibiting imposition of sanitary and phytosanitary measures without demonstrating clear scientific evidence of risk. Developing countries also resist cultivation of biotech products, for fear that their exports to the EU (a large market for poor countries’ exports) will be resisted if ‘tainted’ by bio-engineering techniques. More specifically, it is said that the EU’s moratorium is inconsistent with WTO rules, including the Agreement on Sanitary and Phytosanitary Standards (the SPS Agreement), the Agreement on Technical Barriers to Trade (the TBT Agreement), the Agriculture Agreement and GATT 1994, in that Europe’s own scientific studies have not produced adequate risk assessments that biotech products are harmful to human health or the environment. The SPS Agreement, for example, recognises that countries are entitled to regulate food products to protect human health and the environment, but requires measures imposed to carry out these non-trade objectives to be based on ‘sufficient scientific evidence’, and approval procedures to be carried out without ‘undue delay’. The allegation is that SPS measures, if not based on a proper assessment of risk and function, are disguised barriers to trade.

58 Ibid.
Howse & Mavroidis in an interesting article\(^{60}\) consider how restrictions on genetically modified organisms would be judged by a WTO panel. It remains to be seen whether their analysis will be prescient. What is sure is that the European Union has not been convincingly successful in arguing before international for a that prohibitory measures were legitimately based on science, but that its efforts in Luxembourg have been more successful.

10. THE ANTIBIOTICS LITIGATION IN LUXEMBOURG

This brings us to the recent controversy about the banning of four antibiotic feed additives. I repeat that as an advocate involved in those cases, my views are unreliable; I am perfectly content to cook meat from chicken which has been reared without the use of virginiamycin (although other antibiotics may have been used, either because the bird was reared in the United States or because authorised antibiotics had been used in its production); and no citizen can object to society’s reaching a policy decision after mature and frank debate. It is also quite possible that the controversy has been salutary, and that the Institutions have learned from it: on 22 July 2003 (long after this book should have gone to press), the Commission announced that the four remaining antibiotic growth promoters (monensin sodium, salinomycin sodium, avilamycin, flavophospholipol) would be phased out, not as an emergency measure but as part of a general food strategy.

11. CAMPAIGN TO REDUCE THE USE OF ANTIBIOTICS, NOTABLY IN SCANDINAVIA

The Nordic countries have a commendable commitment to high environmental standards. For some years they have pursued a policy of encouraging the phasing out of antibiotic growth promoters, as part of a general scheme to make animal husbandry more wholesome. The results of this policy were not consistently positive: the therapeutic use of antibiotics on herds and flocks rose (prophylactic use in tiny doses helped avoid common diseases, as well as making the animals thrive), and there was an increase in the use of alternative treatments, which have their own adverse environmental consequences. However, the policy enjoyed broad popular support. During their accession negotiations, the governments of Sweden and Finland obtained a prolongation, until January 1999, of the deadline by which they would have to accept the use of antibiotic growth promoters, or the Community regime would be adapted, or an extension of the temporary ban would be made. It was expected that by January 1999 the Community would have reached a definitive view on the products.

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Critics asserted that the use of antibiotic growth promoters in animal husbandry might have the effect of hindering the delivery of effective medical care to patients infected by an organism resistant to the antibiotics fed to animals, as that organism would also be resistant to other powerful antibiotics in the same chemical family. (Antibiotics exist in families, and public health policy has been to discourage the use of antibiotics in the same family both for human use and for animal non-therapeutic use. Virginiamycin is in the streptogramin family.) There was a robust debate in which one side said there was a danger and the other said there was no need to change as the risks had been taken into account when the products were authorised, and were in any event remote, whereas the benefits to farmers were certain.

Each of us has inside our body millions of Enterococi faecium—not resistant to antibiotics—which help to digest our food. It is possible that in the gut of some human beings today dwell colonies of E. faecium which acquired resistance to the antibiotic virginiamycin. Such resistant E. faecium might have entered those intestinal tracts through the presence, on undercooked chicken meat, of living enterococci from chicken faeces dropped on the surface of that meat after slaughter. This eventuality cannot be disproved. Someone could in 1998 have bought frozen chicken which had been reared on a farm in Spain that used virginiamycin as a feedstuff additive, and the meat could have contained some E. faecium resistant to antibiotics of the streptogramins family, so that the consumer, when having a liver transplant operation, then fell victim to an infection which could not be cured other than by the use of another streptogramin such as the human medicine synergide. If the patient had acquired resistance to all streptogramin antibiotics, they would be ineffective to cure the infection. Nevertheless, in recorded human medical science, no patient’s treatment has ever been compromised due to resistance attributable to virginiamycin. The products have been used in Europe for approximately thirty years.61 No one fell ill, so far as is known. In France, the streptogramin antibiotic pristinamycin was used for decades in human medicine, and virginiamycin was used in animal feed, with no significant change in either the incidence of the effectiveness of the human medicine, or the incidence of resistance in humans to streptogramins.62 Researchers have sought such proof of harm, but they have not found it.

It is not disputed that the principal cause of the grave medical problem of human antibiotic resistance is the excessive use of antibiotics in human medicine.63 There is a whole branch of medical science devoted to preventing and

61 The danger of acquiring a resistance to antibiotics, called ‘a hazard of enormous severity… a nightmare…’ was eliminated as to purchases of European chicken meat by the Regulation. However, this danger continues to haunt chicken meat imported from Hong Kong or the United States, perhaps because of the very fact that WTO standards as to scientific proof are stricter than EU standards.

62 A major study was under way in 1999 in several Member States to ascertain the level of resistance in food animals to particular antibiotics due to the use of antibiotic feed additives, but the study was not completed due to the ban.

63 US consumption of one antibiotic was 1000% higher than that of the Netherlands per head of the population.
controlling hospital-borne infections. Professor Casewell, one of the scientists who gave evidence for the producers, was a founder and Chairman of the Hospital Infection Society, and could describe from personal knowledge and experience how hospitals (where patients are most at risk from opportunistic infections by bacteria which have grown stronger and stronger through unsuccessful efforts to kill them) have analysed and responded to multiple-resistant organisms. For example, washing the walls of operating theatres with antibiotic liquid and using antibiotic soap each turned out to make hospital infections more difficult to manage. No friend of laxity in the use of antibiotics, he criticised the scientific rigour of the challenges to antibiotic feed additives in 1998 and earlier years.

The prohibition of the four products covered by the contested Regulation started with a Danish prohibition in January 1998 of virginiamycin feedstuffs, taken on the basis of the emergency procedure under Article 11 of Directive 70/524/EEC. The Danish ban lacked technical evidence, and the Commission requested data. In February 1998 the Kingdom of Sweden requested to be allowed to maintain its ban after December 1999. The Danish authorities produced further evidence in March and April 1998 which was again challenged by the industry. There was no consensus among the Member State delegates on the working group responsible for deciding animal feed controversies.

The matter was submitted to the Scientific Committee on Animal Nutrition (SCAN), which gave its opinion that, as to virginiamycin, the evidence advanced for its consideration did not justify a prohibition of the products. An additional piece of evidence offered in the course of 1998, an experiment on germ-free rats, demonstrated that resistant E. faecium would conjugate in the intestinal tract of a germ-free rat, and could transfer resistant characteristics to other enterococci. The European Commission relied upon this rat experiment as ‘major fresh evidence’ as to virginiamycin which obliged it to act quickly for the protection of public health. The SCAN was not asked to opine upon this new evidence. The SCAN was not consulted on whether the use of bacitracin zinc as a feed additive presented a threat to public health. The Commission recommended a ban to the Council, which adopted that recommendation after a vote.

The Court of First Instance considered the matter in detail from January 1999 to September 2002. The manufacturers argued that the Regulation had several vices. Firstly, the authorities chose to ignore official scientific advice whose contents were unwelcome (virginiamycin), or they did not seek advice (bacitracin zinc); secondly, the Regulation justifying action and imposing a ban failed to present the scientific evidence fairly; thirdly, the debate and the decision improperly mingled the policy discussion as to the desirability of the products with whether an emergency existed, and failed to follow proper procedures. (If the Regulation had recorded all the material evidence on both sides and then announced that a ban would be phased in over a period of time, the decision would have been almost immune from judicial review.) Those arguments were rejected in a very lengthy judgment of 519 paragraphs which offered
some admirable statements of principle that will doubtless be invoked in future cases:

‘172. . . . a scientific risk assessment carried out as thoroughly as possible on the basis of scientific advice founded on the principles of excellence, transparency and independence is an important procedural guarantee whose purpose is to ensure the scientific objectivity of the measures adopted and preclude any arbitrary measures.’

12. HOW TO HANDLE OFFICIAL SCIENTIFIC ADVICE

‘It is the customary fate of new truths to begin as heresies and to end as superstitions.’

When considering how the precautionary principle should be applied, there are no ‘proof on the balance of probabilities’ or ‘proof beyond a reasonable doubt’ evidentiary standards on which civil and criminal courts might rely. That is understandable. The Court found that the Community Institutions were entitled not to follow the advice of their own scientists in the virginiamycin case (they were not even consulted as to bacitracin zinc). It was only advice, and of course was not binding. The Institutions are entitled to prefer a minority view to a majority view, provided the minority view has at least some evidentiary basis and is not pure hypothesis. There is no filtration mechanism or standard of respectability which must be satisfied before evidence against a product can lawfully be relied upon. The constraint that a ban cannot be founded on ‘mere hypotheses that have not been scientifically confirmed’ is helpful, but may not represent much of a restriction since many hypotheses have some confirming evidence. Officials may decide whether they will pick mainstream or sidestream sentiment as the scientific basis of an administrative decision or recommendation.

Tens of thousands of the Internet’s websites deal with medical matters. Having studied the information provided by some of these medical websites the President of South Africa, Mr. Mbeki, believes that there is no proven link between HIV and AIDS. This may be a minority view, but it cannot be definitively proved wrong. The public health policy of his country appears to have been damaged or at least adversely affected by his espousal of this opinion. Administrative decisions affecting public health have been taken as a result of this eminent politician’s minority view of medico-scientific issues.

13. THE SELECTION OF THE LEVEL OF RISK AS A POLICY, NOT A SCIENTIFIC, CHOICE

The decisive factor for determining whether the threat is serious enough is not a scientist’s choice, but the Institutions’ political judgment of what risks society

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64 TH Huxley.
should accept. Although the Institutions must not base their decision on zero risk, they must take account of their obligation to ensure a level of human health protection which 'does not necessarily have to be the highest that is technically possible'. While setting zero risk as a target would be unacceptable, even the lowest imaginable level of risk from a product—or the technical inadequacies of the Member States in handling its problems—would justify banning it. The ban might be necessary to pursue the highest technically feasible levels of safety.

Thus considerations labelled 'scientific' (not religious, not humanitarian, not trade-related) and based on some assertions in the scientific literature can justify a prohibition on precautionary grounds. No distinction need be made between such a prohibition as an emergency step or as a long-term legislative choice. Whether it is temporary or permanent elimination of a product that is contemplated, the same levels of hypothesis or anxiety based on scientific opinions may suffice. The scientific risk assessment must merely allow the politicians to conclude that there is a risk to human health, even if it is small. The politicians can then determine that as a matter of public policy this level of risk is too high to be acceptable, and ban the product.

Much depends on how the public authority assesses the acceptable level of risk in a complex scientific matter where it clearly lacks scientific expertise. The Institutions have created new scientific committees to assist the Commission in assessing the quality, safety and efficacy of pharmaceutical and veterinary products; yet they themselves do not treat those committees' opinions and findings as a priori reliable, and do not always even take advantage of their expertise. Instead, the scientifically demonstrated existence of not fanciful risks is enough. Then it is a policy, and a political, decision whether this level of risk is acceptable or not.

14. FREEDOM TO SELECT FROM A RANGE OF OPINIONS

'Lest men suspect your tale untrue, keep probability in view'66

The Institutions are free to disregard a scientific opinion, in whole or in part, if they can find 'other evidence, whose probative value is at least commensurate with that of the opinion concerned'.67 They can do the same to other opinions also. There was debate during the case as to whether government scientists could themselves constitute the scientific input which the Court says is necessary.68 In Alpharma, where there was no SCAN opinion, the Court goes fur-

65 Or alleged, or suggested.
66 John Gay, The Painter who pleased everybody or nobody.
67 Above n 5, Pfizer, para 199.
68 Reference was made to Case C-212/91 Angelopharm GmbH v. Freie und Hansestadt Hamburg [1994] ECR I-171, in which the Court of Justice held that, pursuant to the Cosmetics Directive, the Commission was obliged to consult the Scientific Committee on Cosmetology before taking a decision as it lacked the necessary scientific resources itself.
ther\textsuperscript{69} to allow reliance on the report of the scientists from the country which wished to impose the ban. This seems difficult to reconcile with what the Court said to the effect that a scientific risk assessment should be founded on scientific advice which is in turn founded on ‘... independence ... to ensure the scientific objectivity of the measures adopted and preclude any arbitrary measures’.\textsuperscript{70}

It would be a pity if scientific considerations, and scientific anxieties as felt by amateur or non-mainstream scientists, became subservient to policy considerations. There can be no constitutional objection to the proposition that scientists analyse, consult, report and advise on what the risks are, while political decision-makers decide. But by what standard should they decide? The less a decision to ban is informed by science according to well-defined parameters, the more likely it is to be bad. For regulated industry products (and for those who depend on those products), the risk that a decision to ban if a controversy arises will be bad is particularly high. Once there is some evidence (albeit challenged by other scientists) of a degree of risk, the political class may act on that evidence if the unacceptable level of risk is set at a sufficiently low level.

15. THE ROLE OF THE EUROPEAN COURTS

Judges are not equipped to make social or policy choices, and understandably refrain from doing so. It was no surprise that the Court stated that judicial review must be limited given the highly complex scientific controversies. ‘Light judicial review’ is a familiar feature of the case-law of the European Courts: judges examine légalité not opportunité. The Court also found that the Commission needed the assistance of the relevant scientific committee (save in exceptional circumstances) because of the complexity of the facts.\textsuperscript{71} Thus the Institutions cannot be expected to work out the science themselves and need scientists to guide them. But they nevertheless have a very wide discretion to decide how they will interpret that science (and which science to select) to reach decisions. The discretion which the authorities enjoy is particularly wide when read in the light of the limited amount of scientific literature needed before a ban can be considered. Those decisions should be subject to only limited judicial review because judges, even if they can understand such controversies, are not equipped to settle them. If two professors of medicine disagree on a scientific point, either European Court will be reluctant to decide that point if public health is said to be at stake. I observe that national courts decide cases on medical negligence and that both European Courts are ready to challenge expert economists in competition cases, so more judicial boldness might emerge!

While the comitology regime compels close consultation between governments and their regular cooperation with the EU, it reserves them the right to

\textsuperscript{69} Ibid., Alpharma, paras 299-302.
\textsuperscript{70} This had been clarified in Angelopharm, but bears repetition.
\textsuperscript{71} Above n 5, Pfizer, para 270.
act independently in emergencies. Let us imagine that some (national) scientific experts identified a (non-hypothetical) risk—for example, that cheese made from the milk of cows which had consumed genetically modified grasses poses a threat to biodiversity. If one government scientist considers that such a product presents risks for the public, and his view becomes government policy, it will offer a basis for a policy/political decision to impose a ban at least nationally, even if a large majority of other government scientists are of a different view. This is not to argue that a lone voice should be disregarded; but the scientific world's practices of peer review and replication of experimental findings ensure that in the field of scientific discovery a lone voice whose results are sound will soon cease to be a lone voice. The Court considered such a Member State authority sufficiently knowledgeable to be able to pick which parts of which scientific advice it wishes to follow. On this basis, the Commission did not disregard the experts' opinion, but rather adopted a different opinion on the science. The Commission need not offer reasons of commensurate scientific weight with the advice of its own scientists when deciding to disregard their advice, or to follow alternative scientific views.

16. THE DISTORTION OF SCIENTIFIC EVIDENCE

The terms in which the Regulation was drafted were offensive to a number of members of the SCAN. They communicated their displeasure to the Secretariat of the Committee, suggesting that the Regulation misrepresented their scientific advice. The Vice-Chairman of the SCAN was so stirred that he offered to give testimony on behalf of the manufacturer of virginiamycin, Pfizer Animal Health, to the European Court in support of the challenge to the legality of the ban on virginiamycin. He wrote a fourteen-page critique of the Regulation, asserting that it distorted and misrepresented what the SCAN scientists had said in their report to the Commission, and that the ban was precipitate and disproportionate, based on speculation and weak evidence. His subsequent comments to the Court were also extensive. The Vice-Chairman was then summoned to Brussels and dismissed from his position for having publicly criticised the Council's decision. One of the linguistic distortions complained of was recital 9: the Regulation stated the SCAN said '[the risk] could be expected to be demonstrated' when the sense of the SCAN's words was in fact the opposite: if there really was a risk 'it could be expected to be demonstrated', yet no demonstration had been forthcoming. The Court did not need to address this question in its judgment, as the alleged distortion concerned another product whose producer did not appeal.
In the event that a product is eliminated, there are consequences for society. Jobs are lost. Costs go up or go down. Alternatives are used. New products emerge. Former modes of operating change or disappear. Foretelling these consequences is almost impossible. Proponents and opponents will each envisage dire things if their view is rejected. It is wrong to assume society will be better off for the banning of a controversial product. It may be, but this is not sure. Justifying a ban by looking at the elimination of one hypothetical danger is incomplete, even if it is understandable. There are a number of sources which indicate animals are in worse health following the ban.\textsuperscript{72}

The precautionary principle is a reaction to the necessity for officials or political leaders to make decisions in controversial disputes in which public safety is said to be involved and almost always is involved. The most prudent (speaking sociologically and politically) reaction of the regulator is to ban the product. That will lead to fewer criticisms, most of those emanating from discontented manufacturers who can be criticised as profiteers uninterested in public health. Lost opportunity costs are not easily demonstrated.

One problem of the precautionary principle relates to the setting of standards. A standard may mean selecting a maximum level of a dangerous substance in a product used frequently in daily life; it may mean choosing whether to accept any presence of that substance; or it may mean deciding to ban a product in light of dangers possibly associated with it. The decision-maker has to choose whether to allow products which contain some level of a substance deemed harmful. What level to allow? Should cadmium or dioxin or aflatoxin be wholly absent, or should a certain presence be tolerated? Ill-applied, the precautionary principle could deny society access to valuable products which might prolong active life, make work easier, improve food production or enhance enjoyment.

Sometimes European Community policy in an area serves a hidden agenda. Competition law has served, or been said to serve, industrial policy. Fisheries policy has not done very much to help fisheries conservation, but it has probably helped regional integration by offering Southern European fishermen the chance to catch fish in northern waters where conservation policies have been stricter. I speculate whether the precautionary principle too may serve a hidden agenda, perhaps by responding to the techno-sceptic ‘green’ wing of society which doubts what we are told by industry and government about the impact of man upon our environment. Appearing to take action which appears to protect the

public is not an illegitimate government activity. The higher levels of environmental, health and other protection applied in Sweden and Finland were the subject of special attention during the negotiations leading to those countries' accession. They are free to pursue especially high standards in those areas, and very properly commend them in policy-making debates. Can such standards be 'exported' to the rest of Europe? The difficult question is to decide when a controversy relates to conflicting policies where reasonable men may reasonably differ, or to a concrete threat where decisive action is indeed necessary.

18. TO BAN OR NOT TO BAN? THE DIFFICULTY OF QUANTIFYING HOW BAD THE RISKS ARE, AND SIMPLICITY OF DECIDING TO BAN LEST WORSE HAPPEN

'If we wait for threats to fully materialize, we will have waited too long'\(^ 73\)

'Are there new and definite findings and facts? Does the threat assessment justify taking a very high risk?'\(^ 74\)

It seems inevitable that the final decisions will be taken by non-scientists. The universe of preoccupations which non-scientists bear in mind when making a decision is different from the universe of those who look at matters from a purely scientific point of view. Unfortunately, a non-scientist will have difficulty in quantifying or digesting evidence or reports or press articles when scientific issues are involved, the more so as the debate is likely to be coloured, or at least nurtured, by factions, such as those which make or sell the product, and environmental, consumer, press and other groups.\(^ 75\) The risk of media pressure on the political decision-makers is high; at best, it will make it harder for them to examine the matter soberly and assess the risk objectively. Pressure of this kind is especially relevant to procedural scrupulousness. Hence the requirement for transparency. Scientific input is essential, but it will be wasted if the decision-maker is then allowed to manipulate the scientific contribution. The only acceptable standard of decision-making is one which neutrally seeks input, assesses it, and then describes fairly what it has been told.

It seems that constitutionally, Europe would not be willing to allow European scientists to make decisions without political supervision, and it is not yet ready to ascribe to them as much weight as they are accorded in rule-making in the United States. The precautionary principle is here to stay. This should not, however, deter lawyers and those engaged in other disciplines from drawing attention to its implications and possible weaknesses.

\(^{73}\) President George W. Bush, speech to the graduating class at West Point, 1 June 2002.

\(^{74}\) German Foreign Minister Joschka Fischer to the UN General Assembly, 14 September 2002.

\(^{75}\) The Royal Society, the national academy of sciences in the UK, has launched an enquiry chaired by Professor Sir Patrick Bateson about how and when scientists communicate their research results to the public, and whether scientists should check each other’s work before it is published.
The precautionary principle has a built-in tendency to favour the banning of a product which is controversial. The evidence may not be fairly presented, it may have been poorly compiled, or the statistical conclusions drawn from it may be exaggerated, but there will not usually be no evidence at all. The decision-maker will be encouraged to ban the product and thereby protect human health and safety. Because of public attitudes, politicians risk less if they prohibit and more if they refuse to do so. The administrator who has to make the final decision will feel safer and more prudent if he elects to ban than if he elects not to ban. Assuaging public concern is one of the functions of a political leader. Unfortunately, being told that experts are confident in a product does not assuage public concern.

Civil servants and lawyers may have a role to play in assisting the decision-maker to reach a decision. The civil servant's role should be to endeavour to enhance the quality of the political decision which he is helping to prepare. Civil servants sometimes receive a political mandate from the decision-maker with the instruction to produce grounds to support that conclusion.

The European Courts control the legality of the administrative process, and have a tradition of not substituting their own sentiment for the lawfully-exercised discretion of politicians and civil servants. This would not, though preventing the European Courts from demanding the same level of scrupulousness and rigour in fact-gathering and fact-describing from the European Institutions as would be required in competition cases, and from being equally ready to disagree with the Institutions in competition cases.

19. HIGHLY REGULATED PRODUCTS

What about products which were subject to heavy regulatory control before they reached the market? Should they be deemed liable to be banned on precautionary principle grounds? Should they be immune from the precautionary principle altogether? Would the problem of the precautionary principle be solved if it was not applied to products whose putting on the market involved exhaustive regulation? To what extent does exhaustive pre-marketing regulation ipso facto involve the application of the precautionary principle? May one argue that regulated products represent a special case, the very expression, as it were, of the observance of the precautionary principle? Such products reach the marketplace only after passing through an elaborate and exhaustive series of tests to demonstrate their safety and efficacy: years of testing in the laboratory, on animals, on healthy human volunteers, on selected volunteer patients, and on hundreds or thousands of patients in clinical trials. It will have side effects in some cases and

76 Moreover, banning involves exercising his authority, which accepting the status quo does not; and the exercise of authority is often not disagreeable, since taking action is commonly preferable to not taking action.
the potential for causing harm. It will never offer society unalloyed and unequivocally benign consequences—indeed, in many cases its deleterious effects are a necessary counterpart of its therapeutic benefits. The merits and demerits of the product will have been appraised and balanced by those who have the scientific, technical, social or other knowledge for this essential task, and authorisation granted only after they have carried it out.

Prohibiting such a product, after it has passed through this elaborate process, may reflect either society’s conclusion that the original balance of risk and benefit needs to be recalibrated, or society’s concern that the product, contrary to its original appraisal, presents an urgent danger. Prohibition on the first ground may indeed be justified—everyone makes mistakes, and science can offer clarity—but its passage should not be smoothed by claiming that it was required by the second ground.

This critic of the Commission’s approach to the precautionary principle would regret that it is not the scientific substance of the fears that triggers the ban, but the political decision that what is feared offers a serious threat to society. Scientific input is therefore presented as one of several equally valid ‘readings’ of the world. The precautionary principle should return to its roots: the idea that action should not wait until concrete proof of causality is present, rather than allowing minimal evidence of a risk to justify action. Whereas critics are not under any serious obligation to substantiate their allegations, the innovators are often faced with enormous costs.

20. CONCLUDING REMARKS

The subject of this article has been extremely difficult for this author to grasp. The disciplines of the scientist, the epidemiologist, the civil servant, the judge and the lawyer are each relevant. I offer no magic formula for the future for the taking of decisions in precautionary principle controversies, but I do modestly submit that how decisions have been taken in the past is imperfect. The European Institutions appear particularly vulnerable, because of a variety of factors, to media pressure and imperfectly robust analysis of genuinely painful choices. I do not expect that in the foreseeable future we will have a world where scientists alone are given the right to decide on whether a product should be banned or not banned; anyway, scientists are not immune to error, policy preoccupations, obstinacy or naivety. It would appear that decisions are going to continue to be made on the basis of recommendations from civil servants to political leaders. I offer some suggestions.

There should be greater clarity as to what is the role of the civil servant with a scientific training: is he an advocate or an advisor or a decision maker to be guided by other experts?

There should be continued judicial rigour in demanding scrupulous respect for applicable procedures.
The European Courts may reconsider whether it is desirable that the political class set the standard of risk which they deem society should be willing to accept, without ensuring that such level corresponds to an opinion shared by mainstream scientific opinion.

The precautionary principle should not become an excuse for failing to address controversy fairly; nor should it be invoked where no other doctrine fits.

There is a vast body of literature on this subject, which is of interest and importance, and I regret that very few lawyers in their regular practice have the privilege of becoming involved in such controversies. I also regret never having had the chance to argue one of these cases before Judge Edward, the person in whose honour this book has been compiled.