Regulating Risk Regulation

How the Court of Justice ensures the European Community responds to both popular and scientific voices

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In a string of challenges to EC regulations that culminated, in the last five years, in Pfizer and Alpharma, on the safety of feeding growth-inducing antibiotics to farm animals, Artegodan, on the safety of a diet pill to induce weight loss in humans, and Alliance for Natural Health, on the safety of dietary supplements, the ECJ reveals an increasingly sophisticated understanding of the capacity and limitations of using scientific expertise to legitimise risk regulation. These cases set out a number of important principles that determine the bounds within which the EC and its institutions go about regulating risk and mark out distinct roles for its specialist regulatory agencies, its scientific and comitology committees and its more democratically accountable institutions, which are each attuned to hear, consider and respond to differing (often conflicting) voices and their underlying rationalities that are categorised loosely as being either popular or scientific.

Introduction

Few would dispute that regulation must hear, consider and respond appropriately to both popular and scientific voices and their underlying rationalities, but deciding what is appropriate when these urge in different directions (as they often do) is more difficult. Just as the Commission reveals its understanding of the appropriate blend, with its tendency to see scientific expertise as a panacea for regulatory legitimacy, the Court of Justice and the Court of First Instance (hereinafter, simply “the Court”) reveals much about their own understanding in a string of cases that involve challenges to the Community’s regulation of various scientifically uncertain risks. It is illuminating to explore the development (and increasing sophistication) of the Court’s understanding of the role of science in the regulatory process, through a series of cases that started with Fedesa¹ and Angelopharm,² in the early 1990s, and led on to a second generation of cases, a decade later, in Pfizer,³ Alpharma,⁴ Artegodan⁵ and Alliance for Natural

¹ Middlesex University Business School.
These cases show that it is too lazy to dismiss what the Court does as imbuing scientific expertise with some ‘metaphysical status’. Rather, they show a more nuanced appreciation of science’s capacity to legitimise regulatory power, as well as its limitations in doing so. The Court has used them to mark out the roles of the Community’s scientific and comitology committees, its agencies and its institutions, and this has had a significant bearing on the way popular and scientific voices feed into the regulatory process because each of these actors are attuned to hear different voices.

This article describes a number of regulatory episodes and the Court’s reactions to them, starting with a story that spanned the 1980s, in which the Community sought to ban the use of hormones in livestock farming and was twice reviewed by the Court, moving onto bans on a hair tonic and a suntan lotion that were legally challenged in the mid-1990s and finishing with the Community’s handling of the BSE crisis and the judicial response to it, which is a story that rumbled on throughout the 1990s. This first generation of cases sets the context for a second generation, in the last five years, in which the Court has scrutinised the Community’s ban on antibiotics as animal growth promoters and, more recently, a diet pill and a number of food supplements. It is in these cases in particular that one discerns an advanced understanding of science’s capacity and limitations in legitimising regulatory power.

**Beef hormones**

In the late 1970s, an Italian magazine ran a story about babies developing abnormally large genitals and young girls starting to menstruate, having eaten baby food made from French veal containing traces of a synthetic hormone used illegally to promote the calves’ growth. The media across Europe quickly latched onto the story, which had all the right ingredients to sell newspapers (commercial greed, consumer vulnerability and administrative incompetence) and reports flashed around Europe about how school lunches were causing sexual abnormalities in children. Alarmed by the fact that it was the media, rather than the regulatory authorities that had uncovered the illegal practice, as well as by the failure of the authorities to inform consumers properly, the public was unconvinced by their national government’s reassurances and stopped buying veal. With concern growing about the use of hormones in farming in general (whether administered legally or illegally) a slump occurred across the entire beef market and the Commission, as the coordinator of the Common Agricultural Policy (CAP), had to be seen to act.

Notwithstanding the lack of scientific evidence of any risks associated with the use of hormones in this way, provided they were administered within the legally-permitted doses, the Commission was bounced into proposing a Community-wide ban on three natural and two synthetic hormones, which the Council adopted in 1981.  

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7 M. Everson ‘Adjudicating the market’ (2002) 8 ELJ 152, 162.

8 Dir 81/602.
the Community’s scientific working group set up to look at the evidence in detail concluded that the natural hormones indeed presented no danger to public health (when administered properly) and that further research was needed on the synthetic hormones. In fact, from the early 1980s until today, popular opposition to the use of hormones in farming has been as consistent as the failure of the scientists to turn up convincing evidence to substantiate the public fear that the practice presents a health risk. So, although the Community’s Scientific Committee for Veterinary Measures concluded unanimously, in 1999, after years of extensive research, that there was no evidence to substantiate any danger, every single political party represented in the European Parliament supported the refusal to lift the ban on US beef, which had been excluded from European markets as a knock on effect of the ban (hormones are used extensively by US farmers).

Responding to the scientific findings, the Commission reconsidered and proposed to relax the Community’s ban by re-allowing the controlled use of the natural hormones and re-examining the ban on the two synthetic hormones, but its move was opposed by a number of consumer groups, as well as by the Economic and Social Committee and the European Parliament, which was beginning to flex its muscles as it started out on its second term as a directly elected institution. They had all latched onto the issue as one resonating with public concerns that they might use to cut their political teeth by spoiling for a fight with the Commission, in which they knew they had public backing. They stood firm and the Commission blinked. It cancelled further meetings of the scientific working group and had little choice but to reverse its proposal to relax the ban and even exchange it for one that extended to the one natural hormone that was then still permitted. The Council adopted the proposal by qualified majority under the agricultural title, opposed by the UK, which objected to its lack of scientific basis. And thus began a lengthy legal saga, which was shunted from one court to the next, appearing in all sorts of guises, and eventually found its way to the WTO’s Appellate Body via a challenge from the US. Much of the story is beyond the scope of this article but its length nonetheless stands as testimony to the high stakes, the acrimony that surrounded it and the difficulty of finding an acceptable resolution.

But, returning to the beginning of the legal saga, the UK challenged the Council’s ban in the mid-1980s, on the basis that it failed to take into account the scientific report on the use of hormones prepared according to the relevant Directive by the Community’s scientists who had concluded that the hormones would result in no significant harm if administered following good veterinary practices. Though the Court rejected this ground on the technical point that the Directive only imposed an obligation on the Commission to take the scientists’ report into consideration (and not the Council, which had in fact adopted the ban), it upheld the challenge on another procedural nicety that the UK had

10 Dir 88/299.
12 Dir 85/649.
14 Art 8, Dir 81/602.
never consented to a written vote (even though the ban only required and had obtained, albeit in an impermissible form, a qualified majority).\textsuperscript{15}

The UK’s success proved a short-lived obstacle because the Council immediately adopted an identically-worded ban,\textsuperscript{16} (again by a qualified majority, but this time following the correct procedure) which was itself subject to an unsuccessful legal challenge by an association of veterinary medicine manufacturers representing the companies whose hormones had been banned. Unlike the technical challenge to the ban’s predecessor, \textit{Fedesa} went to its substance (rationality, scientific justification etc). In rejecting the challenge, the Court credits the Council with a great deal of discretion when implementing CAP. It states that it would only overturn a ban that was ‘vitiated by a manifest error or misuse of powers’ or if the Council had ‘manifestly exceeded the limits of its discretion’.\textsuperscript{17} But the significance of \textit{Fedesa} extends way beyond the Community’s administration of CAP because the Court, for the first time, addresses itself in detail to the appropriate role of science in the exercise of the Community’s regulatory powers. At the same time, although it is innovative in some ways, it can also be seen alongside three existing trends because it (1) (implicitly) bolsters the authority of the European Parliament; (2) avoids overturning a popular piece of Community legislation, despite its flimsy scientific credentials; and (3) shows greater deference towards the Community’s regulatory powers than the Member States have come to expect from it when their regulations are challenged.\textsuperscript{18}

Without examining the scientific evidence in detail, the Court simply assumes it was inconclusive from the fact that the Member States were unable to agree on their assessments of it. From this, it concludes that the Council could not have regulated on the basis of the scientific evidence alone because, whilst the issue raised questions that could be asked of science, science was incapable of answering them on its own, making the issue trans-scientific.\textsuperscript{19} From this it concludes that it was appropriate to cut the Council some slack and allow it to respond to concerns expressed by the European Parliament, the Economic and Social Committee and consumer organizations,\textsuperscript{20} which are all institutions that are more attuned to popular than to scientific voices. In that sense, \textit{Fedesa} belongs with a cluster of cases around the same time in which the Court pulled in behind the European Parliament, which had recently acquired a stronger democratic mandate by virtue of its directly elected status, to strengthen its institutional power, both as a litigant\textsuperscript{21} – which the Parliament was quick to exploit as a political strategy\textsuperscript{22} – and as a

\textsuperscript{16} Dir 88/146.
\textsuperscript{17} Case C-331/88, \textit{R v Minister for Agriculture, Fisheries and Food ex p Fedesa} [1990] ECR I-4023, paragraph 8.
co-legislator, alongside the Council. In *Roquette Frères*, for instance, the Court had bolstered Parliament’s legislative authority, not only to uphold the institutional balance established by the Treaty, but explicitly to reinforce the ‘fundamental democratic principle’ of popular participation in the exercise of legislative power. Likewise, in *Fedesa*, it recognises that if the obligation on the Council to consult Parliament is to have any meaning, it must not be made a slave to the scientific advice it receives from the Community’s scientists but must instead have the freedom to respond to the views Parliament expresses, even if these run counter to the prevailing scientific view.

Joerges complains that the disregard for scientific evidence sanctioned by the Court in *Fedesa* ‘can hardly be heralded as a triumph of legitimate political authority over the neglect of public anxieties by insulated technocrats’ because the institutional mechanism it endorses is intergovernmental bargaining in the Council, which ‘should not be equated with deliberative political processes on the social acceptability of technological developments’. But, arguably, his emphasis on the need for scientifically-informed deliberation neglects the fact that such deliberation is only capable of legitimising political authority when it is also informed by popular voices, in this case on the acceptability of using hormones as growth promoters and the attendant risks, which the national governments that make up the Council are capable of bringing to the fore, unlike the Community’s scientists. While it would be inappropriate to amplify popular voices, simply by silencing those of the scientists, the Court in *Fedesa* does not do this, but rather ensured that both were heard when the Community was considering how to exercise its regulatory powers.

A further consequence of the Court recognising the issue as trans-scientific is that it permits the Council to see the decision from a broader perspective and not purely as a scientific matter. To this end, the Court permits the Council to justify its ban with reference to the need to assuage consumer anxieties to the extent necessary to encourage beef consumption. Implicitly, the Court is indicating that it is permissible, in these circumstances, for the Council to respond to the mere presence of popular concern, regardless of its scientific foundation. This fits squarely into a second judicial trend, in which the Court (aware of the precarious popular support for the Community’s regulatory programme in general) has been astute to conspicuously avoid overturning Community measures that enjoy broad popular support, even when they appear dubious in the light of the available scientific evidence. This, to some extent, runs counter to national

26 This was a factor that the Community was not allowed to take into account under WTO rules and which formed the basis of the US challenge.
administrative law traditions where the judiciary has frequently seen it as their job to protect legitimate, but nevertheless unpopular, interests from unjustified government interference, but is appropriate for the Community whose institutions enjoy less background popular support.

By indulging national measures, which hinder free movement with limited scientific justification, less than Community measures aimed at scientifically uncertain risks, which are challenged for lacking scientific evidence, to the point that the Community institutions need adduce only very limited evidence to justify almost any measure, the Court effectively forces the Member States to cooperate with one another to reach agreement at the European level whenever they are determined to placate public concerns that are unsupported by much in the way of scientific evidence. Presumably the Court’s logic is that even if the Community measure appears to lack justification, at least it does not hinder free movement as well.

Weiler tracks the Court’s belief in the ‘epistemic separateness’ of science and politics back to its policing (in its Article 28 jurisprudence27) of the limits to the Member States’ derogations to the free movement guarantees, in which the Court uses a similar construct to camouflage the policy role it plays.28 Here too, the Court attempts to use the same construct as a means to acknowledge the political contention involved in regulating scientifically uncertain risks, without conceding that it too plays a policy role when reviewing these measures. It is an attempt to have its cake and eat it. On the one hand, it uses science as a touchstone for determining the compatibility, or otherwise, of national measures with Community law, as well as a means to defend itself against the charge that when it reviews them it strays into policy-making, but, on the other hand, it draws attention to science’s limitations in dealing with trans-scientific questions in order to justify its deferential review of Community measures that are based on very limited scientific evidence.

The Court requires scientific justification from both national and Community institutions, but not necessarily of the same order. While it applies many of the same principles when reviewing national measures that hinder free movement as it does to the Community measures it is asked to scrutinise, it does so with differing degrees of intensity. It subjects national measures to a more stringent constitutional style review and Community measures to a more deferential, administrative law style review. So, whilst both national and Community institutions operate in the shadow of the Court’s case law, aware that their decisions are potentially subject to its review, Community institutions are subject to the manifest error test, set out in Fedesa – a deferential standard common to administrative judicial review and typified by the Wednesbury reasonableness test in the


UK and the “arbitrary and capricious” test in the US’s Administrative Procedure Act – whereas Member States are subject to a more stringent standard, typical of constitutional judicial review, because this is necessary to further the Community’s underlying “constitutional” purpose of market integration, which demands that the Member States are held strictly to the terms they adjudge an acceptable basis for resolving the inevitable conflicts that will arise. In contrast, when the Court is called upon to review measures enacted by the Community’s institutions it enforces an administrative law that it has itself shaped, which strives to achieve the far more nebulous aim of promoting the legitimacy of those measures.

**Hair tonics and sun-tan lotions**

A few years after refusing to overturn the Council’s ban on the use of hormones in livestock farming, the Court examined the legality of the Commission’s ban on a hair loss tonic, Setaderm, that was feared might present a danger to public health. The Court makes it clear that the ban had to be ‘founded on scientific and technical assessments which must themselves be based on the results of the latest international research’. This time however it found that the Community (in this case the Commission and a comitology committee) lacked the necessary expertise to assess the scientific evidence on their own and, as such, should have sought the assistance of the Community’s scientific committee, whose experts were seconded by the Member States. Although the Court makes it quite clear that the Commission would not have been bound by the scientists’ advice, it does insist that the Commission refer the matter to them, so that their testimony might be heard, without which the ban could not be made from a ‘fully informed position’. Crucially, it considers this obligation to consult scientific expertise stems from ‘the nature of things and apart from any provision laid down to that effect’, supporting the idea that the Court adjusts its case law to perfect imperfections it finds in existing institutional arrangements. Read broadly, Angelopharm stands for the principle that a Community institution must consult the Community’s scientists whenever its take a decision for which it lacks sufficient expertise in its own right, notwithstanding the absence of any formal requirement on it to do so.

The Commission learnt its lesson. 18 months after the Court decided Angelopharm, the Commission consulted and this time heeded the advice of the very same scientific committee it had failed to consult when banning Setaderm, and was thereby able to defend itself successfully against a legal challenge from a company it had forced into liquidation by banning its only product, a suntan-lotion, Bergasol, which drew its name from the herb, bergamot, whose essence it contained and which the scientific committee

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29 Associated Provincial Picture Houses v Wednesbury Corporation [1948] 1 KB 223.
32 Committee on the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Cosmetic Products Sector.
33 Scientific Committee on Cosmetology.
35 *ibid* paragraph 34.
36 *ibid* paragraph 33.
considered, in spite of a great deal of contrary scientific evidence, might contain a carcinogen. In Bergaderm, the Court of First Instance was succinct: The Commission ‘could not be criticised for placing the matter before the Scientific Committee or for complying with that body’s opinion’. So, while Angelopharm made it clear that the scientists must be consulted, even if their advice was not the final word on the matter, Bergaderm sends out the message that the Commission can cover its back by consulting them and following their advice to the letter, though it must also give the affected party ample opportunity to make representations both to it and to the scientific committee.

BSE

By 1990, BSE had become the news story in the UK. Three hundred cases were being reported a week, beef consumption was lower than it had been for decades and the Agriculture Minister though it was a good idea to assemble the media to watch him force-feed a burger to his four year old daughter! But things only got worse. By 1993, eight hundred cases were being reported a week and there was a slow drip of people dying of Creutzfeldt-Jakob disease, to which BSE had been linked. The British public had lost all confidence in assurances from the Ministry for Agriculture whose attempts to shield them from uncertainty had caused it to mislead them. By 1996, the Commission was left with little choice but to ban the exports of cattle, beef and beef products from the UK to the rest of Europe. So, the legal challenge to the ban, by an association representing British farmers, was the culmination of a protracted crisis that had spanned a decade.

The Court of Justice returned its decision in National Farmers’ Union just a couple of months before the Court of First Instance had returned its verdict in Bergaderm and in it, it makes its first concerted attempt to define the ambit of the precautionary principle, which had been incorporated into the Treaty just a few years before. Indeed, although the Commission has subsequently appealed to the Court to flesh out the precautionary principle further, as things stand, the case continues to be one of the few occasions on which the Court has made explicit references to it. Essentially, it signalled that it would use the principle to extend to the Community institutions a deal of discretion whenever they regulate scientifically uncertain risks but, at same time, would continue to require them to exercise a degree of scientific rigor. The Court insists that Community measures must be properly reasoned and will not allow them to be justified by some vague

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37 Bergaderm complained that humans absorb up to ten times as much of the alleged carcinogen in a single day from eating various food products, including grapefruit, limes, bitter oranges, figs, fennel, celery and parsley, than they would from applying Bergasol, which they claimed demonstrated that it is not harmful in its natural form, even if it is in its chemically pure state.
38 Case T-199/96, Bergaderm v Commission [1998] ECR II-2805, paragraph 65 (unsuccessfully appealed in Case C-352/98, Bergaderm v Commission [2000] ECR I-5291, in which the Court of Justice, at paragraph 66, agrees that ‘in delicate and controversial cases the Commission had to have a sufficiently broad discretion’).
39 Dec 96/239.
41 Article 174(2) EC requires that the Community’s environmental policy is based on the precautionary principle.
42 Communication on the precautionary principle (COM/2000/1 final), 10.
reference to the principle. The institutions must be able to point to some scientific evidence that indicates the existence of a potential danger, which the Court considered they were able to do in this case.

The UK was left with no choice but to undertake drastic measures to regain the Community’s confidence in the safety of its beef. And whilst it tried to get its ship back in order by slaughtered millions of cows (the compensation paid to farmers cost billions of euros), it was required to report its progress to the Commission every two weeks. By 1998, the Commission was satisfied that the UK had brought the problem under control and introduced the Date-Based Export Scheme (DBES), which allowed the UK to resume beef exports, provided they were traceable to cattle born in the UK after 1 August 1996 that were between 6 and 30 months old; were born to a cow that had lived for at least another six months and had never developed BSE; had been clearly identifiable throughout their lives and never exposed to a herd with a case of BSE; and were cut in the abattoir in a way that removed the more risky parts. Exports were to begin on 1 August 1999.

France, whose public were still traumatized by the AIDS-contaminated blood scandal, refused to accept DBES beef and referred the matter to its newly-created Food Safety Agency, the Agence Française de Sécurité Sanitaire des Aliments, which, a month later, advised its government that the beef continued to pose a risk, in particular because cattle might become infected other than by the known routes of feed and maternal transmission, which the DBES was designed to counter; that the incubation period might be longer than presumed under the scheme; and that the system for identifying and tracing meat was unreliable. The Commission forwarded these concerns to the Community’s Scientific Steering Committee for its assessment, which exhaustively re-examined the available data and, noting that incidents of BSE were continuing to decline in the UK, which indicated that no other route of infection existed, concluded unanimously that the measures taken by the UK made the risks from DBES beef at least comparable to those associated with beef from other Member States, including that from France.

In November 1999, the Commission formally threatened France with infringement proceedings, whilst continuing to search for a political solution. A number of tripartite meetings between the Commission, France and the UK took place, culminating in them signing a protocol of understanding on the specific issues on which France sought clarification. They also agreed that British beef would be labelled as such. However, the Agence Française refused to play ball and reaffirmed its concerns; stating that it was not entirely satisfied with the UK’s reassurances and that it could not endorse the efficacy of the additional measures contained in the Protocol. It thereby bounced the French government into declaring that it would not lift the ban, which, in turn, left the Commission with little choice but to submit a formal complaint to the Court that, two years later, ruled that France had indeed failed to fulfil its obligations. The Court was however able to duck the underlying substantive issue (whether the Commission should

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43 Art 3, Dec 96/239.
44 Dec 98/692.
45 Dec 99/514.
have re-authorised British beef exports) on the basis that illegality cannot be pleaded as a
defence in infringement proceedings. France had missed its chance when it failed to
raise the purported illegality within two months of the decision’s publication, as required
under the annulment procedure.

While the Commission argues that a Member State cannot ‘by relying on the scientific
opinion of a national body, substitute its own assessment of the risks for that carried out
by the Commission’, at no point, does the Court proclaim, as Joerges suggests it does,
some kind of supremacy doctrine in the field of “science”. The Court did not pick up
on the Commission’s submission and, whilst it notes that the findings of the Agence
Française were contradicted by those of the Community’s Scientific Steering Committee,
it is never so crude as to say that European science “trumps” national science. On the
contrary, it makes it clear that the Community is not bound by the opinion of any
particular scientific body and can make its own assessment of a risk, which might well
see it favour a minority scientific opinion, or the opinion of a national scientific body,
over that of the Community’s own scientists, which is in fact just what the Council did
when it banned the use of certain antibiotics as growth promoters; a decision that the
Court was asked to scrutinise in Pfizer and Alpharma around the same time.

Antibiotics as growth promoters

The hormones saga, which led to the Court of Justice’s ruling in Fedesa, prefigured a
very similar saga, a decade or so later, which this time involved the use of antibiotics as
animal growth promoters and the lengthy rulings, returned on the same day in September
2002 by the Court of First Instance in Pfizer and Alpharma. In both sagas, the scientific
evidence supporting the existence of a health risk was flimsy, but this contrasted
markedly with a pronounced public disquiet about the farming methods at issue.

For as long as we have had antibiotics, scientists have been aware that the bacteria they
treat are capable of developing resistance to them. And, for decades, the pharmaceutical
industry had an obliging cash cow, developing new antibiotics to replace those that had
become ineffective in this way. However, more recently, it has found the task
increasingly difficult because some bacteria, dubbed “hospital super bugs”, including the
infamous MRSA, have mutated to become resistant to ever more antibiotics and are
doing so at a rate that is outstripping its ability to create new, more effective drugs.
Increasingly, the only antibiotics capable of effectively treating these super bugs present

47 Article 230(5) EC.
49 ‘Law, science and the management of risks to health at the national, European and international level:
Stories on baby dummies, mad cows and hormones in beef’ (2001) 7 CJEL 1, 8.
50 Case C-1/00, Commission v France [2001] ECR I-9989, paragraph 89.
52 Methicillin-Resistant Staphylococcus aureus.
serious toxic side-effects. The issue has hit the headlines across Europe, with one tabloid newspaper in the UK reporting that MRSA kills 5000 patients a year in Britain alone.53

As far back as the 1960s, scientists were aware of another side-effect of antibiotics; namely, that adding regular, low doses to animal feed not only reduces their susceptibility to disease, but also the time and feed needed to fatten them for slaughter. The practice became wide-spread in pig and poultry farming. However, in the 1990s, it became caught up with the growing concern about increasing antibiotic resistance in humans when it was shown that infections in animals had also developed resistance to antibiotics as a result of their continual exposure through what animals were being fed. It was feared that this resistance might transfer up the food chain to humans eating their meat, further reducing the effectiveness of antibiotics in human medicine. Nevertheless, the scientific evidence supporting this route of transfer was, and remains, extremely tenuous.54 And, even if it were possible, scientists across-the-board agree that the impact would only be marginal, in comparison to that of the excessive and inappropriate use of antibiotics in human medicine itself, which is universally acknowledged as the fundamental problem.

Although the Community had regulated additives to animal feed since 1970,55 it only responded to popular concern about the addition of antibiotics in the mid-1990s, when Sweden and Finland – both countries that had restricted the practice for some time – acceded to the Union. First up, it introduced an authorisation system under which only those additives that had obtained its prior approval could be added. At the time, this included eight antibiotics.56 The system also incorporated a safeguard clause that allowed individual Member States to ban additives that had been approved by the Community if they could be shown, on the basis of new information or a reassessment of existing information, to present a danger to public health, in which case the Member State had immediately to inform the Commission, giving detailed scientific grounds, which the Commission was obliged to assess with a view to withdrawing the Community’s own authorisation.57

The issue came to a head in 1998 when, in January, Denmark took advantage of the safeguard clause to ban Virginiamycin, which was one of the eight Community-approved antibiotics and had been added to animal feed for 30 years by around half of Europe’s pig and poultry farmers.58 Pfizer was the only producer of Virginiamycin, which it did from a Belgian factory dedicated to the task. In support of its action, Denmark cited a report produced by its National Veterinary Laboratory, which stated that it was unable to exclude the possibility of resistance transferring to human infections via the food chain.59 However, the only positive evidence the report put forward to sustain the possibility was

54 Pfizer, paragraphs 41, 50, 113, 320, 356, 360-1 and 372 and Alpharma, paragraphs 36-7, 41, 134, 273, 279, 281, 287.
55 Dir 70/524, amended by Dir 84/587.
56 Dir 96/51.
57 Art 7 and 11, Dir 70/524.
58 Pfizer, paragraph 466.
59 ibid paragraph 44.
a single instance in which the Laboratory had discovered Virginiamycin-resistant bacteria in both a Dutch farmer and the droppings of one of his turkeys.⁶⁰

A month later, emboldened by growing public concern across Europe, which, in the wake of the BSE crisis was highly sensitised to stories about “dubious” farming practices, Sweden joined a growing chorus of Member States demanding stricter controls. It went further than Denmark and urged the Commission to withdraw authorisation of all eight Community-approved antibiotics, including Bacitracin, which farmers had been using for 40 years and which was produced in Europe exclusively by Alpharma (also Europe’s largest supplier). Sweden already banned all eight, under a special derogation it had secured on joining the Community,⁶¹ but this was due to expire at the end of 1998 and it was determined not to have to give up its ban. The scientific evidence it put forward was every bit as flimsy as that which Denmark relied on and it even conceded that it was too scarce to assess the risk of Bacitracin to public health at all.⁶² Essentially, Denmark and Sweden were determined to ban farmers from using antibiotics in this way and were not going to let any lack of scientific evidence stand in their way. The scientific evidence was not driving the policy but was simply “spun” to fit a policy that had been adopted in spite of the evidence and was preferred for other reasons; a classic example of the adversarial use of science.

First up, the Commission asked the Community’s scientific committee⁶³ to give its opinion on whether the conclusions in the Danish report were ‘scientifically justified’, which it did in July, noting that the ‘anecdotal’ evidence of the Dutch turkey farmer was ‘unsound and without foundation’ and that even if resistance had transferred between the two there was no more proof that it had originated in the turkey and transferred to the farmer than it had travelled in the other direction.⁶⁴ It concluded that the report provided no new evidence or quantitative data to support the theory and was, therefore, under the terms of the safeguard clause, incapable of justifying the ban, especially as Virginiamycin was not used (and was unlikely to be used in the near future) to treat humans in Denmark.⁶⁵ A week later, the Danish government hurriedly submitted another study (this time conducted on rats) which it claimed constituted decisive new evidence. The committee looked at the study and dismissed it summarily⁶⁶ in November as containing ‘major methodological weaknesses’ and ‘gaps in the scientific data’.⁶⁷

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⁶⁰ ibid paragraph 344.
⁶¹ Point E1(4), Annex XV, Title VII, Sweden’s Act of Accession.
⁶² A judgment shared by the comitology committee, which reported a few years later that Bacitracin had been banned before a “thorough scientific evaluation” of its risks had been conducted (Alpharma, paragraph 274).
⁶³ Scientific Committee for Animal Nutrition.
⁶⁴ Pfizer, paragraphs 348 and 371.
⁶⁵ ibid paragraph 53.
⁶⁶ The Court found that the committee’s opinion in this instance did not amount to a formal scientific opinion because it had not followed the required formal procedure and it had failed to provide detailed reasons (Pfizer, paragraph 274 and Alpharma, paragraph 234).
⁶⁷ Pfizer, paragraphs 57 and 350.
In a similar dynamic to the hormones saga, the Commission, mindful of the reassurances offered by the Community’s scientists that the practice was safe, tried to keep a lid on the mounting pressure it was coming under to act, but eventually had to relent. As 1998 drew to a close, the end of Sweden’s derogation loomed and, urged on by the Council, it responded, seemingly reluctantly and against its better judgment, to the public clamour for a ban, instead of the scientific advice. Indeed, the difference in approach between the Commission and Council is revealing in that it reflects the mindset of the two institutions. While the Council is made up of national governments that are highly attuned to public disquiet, the Commission is a bureaucratic institution, more comfortable with committee reports and “objective” science than responding to a clamouring constituency. While the Council urged action to placate the public, the Commission was more resilient and only abandoned its position reluctantly.

The Commission proposed to introduce a limited ban and forwarded a draft proposal to the Council, which, just before Christmas, and with only two weeks left of Sweden’s derogation, withdrew the Community’s authorisation for four of the eight antibiotics – specifically those used both in animal feed and in human medicine – including Virginiamycin and Bacitracin. It had considered banning all eight but settled on the four “dual use” antibiotics, which, for obvious reasons, it considered the most problematic. It promised to review its decision in the light of subsequent scientific evidence.

Pfizer and Alpharma were (understandably) suspicious that the ban on their antibiotics was based more on rumour than good science; a matter of political expediency, in which the Community institutions had sought to placate a public, whose concerns had been whipped up by media scare-mongering and had no scientific foundation. Their legal challenges were not long in coming. Indeed, Professor Pugh, a long-standing member of the scientific committee whose advice had been ignored, was so incensed by the Commission’s disregard that he gave an opinion to Pfizer to use in its legal challenge, in which he complained that the ban reveals the extent to which the Commission’s ‘reforming zeal has outstripped its grasp on reality’ and describes it as a precipitate and disproportionate response … to the urgings of those who have failed to demonstrate the presence of a health problem, but have supplied plentiful speculation and that based on slender and indirect evidence.

But, ironically, the more Pfizer and Alpharma sought to demonstrate that the risks were unproven, the more they revealed contrasting scientific opinions and an uncertain knowledge base, thereby facilitating the Commission’s (and subsequently the Court’s) construction of scientific uncertainty and their recourse to the precautionary principle.

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68 Reg 2821/98.
69 Pfizer, paragraphs 190 and 455 and Alpharma, paragraph 148.
Easing the duty to consult scientific voices

In dismissing Alpharma’s and Pfizer’s challenges, the Court distances itself from the broad precedential reading of Angelopharm, almost to the point of distinguishing the case, and any precedential value it may have had, into extinction. While Angelopharm appeared to place the Community institutions under a wide-ranging duty to consult expertise whenever this appeared indispensable to their decision, regardless of the express terms of the decision-making procedure, Pfizer and Alpharma narrow the application of any such duty to those instances in which the express terms are ambiguous. 71

In Angelopharm itself, the Court of Justice had to interpret a procedure, which required that ‘matters shall be referred … either on [the Commission’s] own initiative or at the request of … a Member State’, 72 which it considered could be read in two ways: either that the scientific committee was to be convened only at the request of the Commission or a Member State, or that it was for one or the other to convene it at their own initiative, but that it must always be consulted. 73 The Court of Justice opted for the second (and, by some distance, the least plausible) interpretation, which the Court of First Instance, in Pfizer and Alpharma, charitably describes as a ‘purposive’ decision. 74 Indeed it was. However, this does not mean, of itself, that the Court of Justice decided Angelopharm wrongly. Behind its choice was the desire to ensure that the Community properly informs itself before exercising its regulatory powers. The Court distorted the procedure’s natural meaning to correct what it perceived to be an imperfection, namely that it failed to set out an obligation to consult when perhaps it might.

In Pfizer and Alpharma, the Court of First Instance not only narrows the principle, which had apparently been established in Angelopharm, restricting it to those instances in which a procedure is ambiguous about the need to consult the Community’s scientists, but it also refused to censure the Community institutions for banning Virginiamycin without waiting for their formal report on Denmark’s second study, which is a clear breach of the express terms of a procedure that put them unambiguously under such an obligation. The Community institutions claimed that the urgency of the matter had forced this upon them, but what is equally clear is that they found the advice they were receiving from the committee hugely inconvenient in the light of the ban the public was clamouring for and preferred instead to avoid receiving what it predicted would be more “unhelpful” advice. Is the Court of First Instance abandoning the process-perfecting tradition here in favour of a more modest, literal or textual approach to interpreting the Community’s procedures, or is this too simplistic a reading?

To answer this question, we must first of all recognise that, although the Court allows the Community institutions to get away with not waiting for the requisite formal report in this instance, it makes it clear that it is making an exception and that, normally, whenever Community institutions are required to assess complex facts of a technical or scientific

71 Pfizer, paragraph 262 and Alpharma, paragraph 207.
72 Art 10(1), Dir 76/768.
74 Pfizer, paragraph 262 and Alpharma, paragraph 207.
nature, it will only allow them to adopt precautionary measures without obtaining the opinion of the Community’s scientists ‘in exceptional circumstances and where there are adequate guarantees of scientific objectivity’.

So, while the Court of First Instance would appear to take a backwards step from the enlightened ruling of the Court of Justice in Angelopharm, in fact its analysis of the role that science plays in the exercise of regulatory power begins to look even more sophisticated, in terms of its appreciation of both science’s limitations when dealing with trans-scientific questions, as well as its strengths and, more especially, its (partially justified) pretensions to universality. The Court of First Instance makes it clear that it does not view the Community institutions’ consultation of the Community’s scientific committees as a simple procedural hoop (which it came close to doing, for instance, in Angelopharm and also in Bergaderm) but will instead examine the quality of all scientific evidence relied upon (and the reasoning from it) regardless of its origin – national, European, or international. This is a nod to science’s aspirations to universality and its fundamentally non-hierarchical character. The Court will assume that the scientific studies – national, European, or international – that the Community institutions rely upon are based on the best available scientific data.

Indeed, it is difficult to see how the Court can be qualified to do anything other than assume scientific objectivity, unless there are clear indications to the contrary. So, whilst the Court continues to oblige the Community institutions to inform themselves properly before exercising their regulatory powers, this does not mean consulting only the Community’s scientists. In this way, Pfizer and Alpharma, though seemingly at odds with Angelopharm, fit comfortably into the same process-perfecting tradition, only, in the decade that separates the cases, the Court had developed a more sophisticated understanding of the role science might play in the exercise of regulatory power.

On the facts, the Court found that the Community institutions had informed themselves adequately and excused them from waiting for the scientific committee’s formal opinion on the second study, on the basis that they were sufficiently well informed by its opinion on the first study; the second study itself; as well as by Pfizer’s comments on it. They refer to the very same uncertainty information, but simply evaluate and weigh it differently. The Court therefore considered that, ‘far from ignoring’ the scientific committee, the Community institutions had relied ‘primarily on certain matters analysed in its [first] opinion’ and had simply developed their own line of reasoning to draw a different (but nonetheless justifiable) conclusion. Likewise, the Court considered that the Community institutions had sufficient information to ban Bacitracin without consulting the scientific committee on the unique risks it presented when used as a animal growth promoter, because it was sufficient that they had access to the committee’s opinion on the other three banned antibiotics; the Swedish study; and the opinions of various international bodies that had studied the dangers associated with using antibiotics as animal growth promoters in general.

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75 Pfizer, paragraph 270 and Alpharma, paragraph 213.
76 Alpharma, paragraphs 222-3.
77 V. Heyvaert ‘Facing the consequences of the precautionary principle in European Community law’ (2006) 31(2) ELRev 185, 198
78 Pfizer, paragraphs 298 and 369.
79 ibid paragraphs 194, 209 and 231.
80 Alpharma, paragraphs 221, 226, 300 and 314-6.
So, though it is clear that the Community institutions seized eagerly upon every hint of scientific uncertainty they were able to find in the scientific committee’s opinion in order to justify the ban that they were determined to introduce, almost in spite of the scientific evidence, they did not pluck that uncertainty out of thin-air. It had some basis in the committee’s report, which provides limited ‘uncertainty information’, even if not systematically. However, the Council stretched credulity when it hailed the second study to be ‘major fresh evidence’, when the committee had found it contained ‘major methodological weaknesses’, ‘gaps in the scientific data’ and brought no ‘new information’. Scientific evidence is always likely to be used adversarially when it enters a political process because it is through this that scientific voices are melded with legitimising popular voices.

Ultimately, the Court considers it appropriate that the Community institutions decide for themselves whether a scientific risk assessment is ‘full, consistent and relevant’ and whether to accept or reject their scientists’ advice (in this case that there was insufficient evidence to justify the ban) provided they explain why they do so, giving reasons of a commensurable scientific level and probative value.

Ladeur criticises the Community’s ban for focusing on a specific risk in a ‘complex field of interrelated elements’ and deplores its neglect of the more pressing risk presented by the inappropriate use of antibiotics in human medicine. This is somewhat unfair because the underlying reason for the discrepancy is that the Community had the competence to regulate animal feed but not how doctors prescribed drugs – a competence zealously guarded by the Member States and exercised across Europe in very different ways. So, while most Member States require patients to obtain a prescription, Spain allows some antibiotics to be sold over the counter, with the result that the Spanish consume nearly three times more antibiotics than the Danish who must obtain a prescription. It is difficult to see how the Community could follow a ‘comprehensive balancing approach’, which is what Ladeur calls for, short of waiting for every Member State to tighten controls on the use of antibiotics in human medicine, before it considered itself entitled to regulate the less pressing risk of antibiotics in animal feed.

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81 eg paragraphs 16-19, preamble, Reg 2821/98.
82 The Scientific Committee for Animal Nutrition report acknowledges, in Section 3, that the “nature of resistance to the streptogramins is not fully understood and mechanisms other than those described … may operate”.
84 Recital 20, Reg 2821/98.
85 Pfizer, paragraph 60.
86 ibid paragraphs 198-9.
While Ladeur’s argument may be entirely reasonable as an appeal to policy makers, he would go further and make his relational rationality legally enforceable upon them. Thankfully, the Court’s position bears no resemblance to what Ladeur would have it do. When Pfizer complains that the Community discriminated against it by failing to act against the inappropriate use of antibiotics in human medicine, the Court gives its argument short shrift, pointing out that ‘there is no equality in illegality’ and that the ban is not unjustified simply because the Community might have banned something else on similar grounds but chose not to. It describes measures to control the use of antibiotics in human medicine as coming ‘under the head of possible further action’ and not as an alternative. Likewise, it was similarly unimpressed by Alpharma’s argument that, instead of banning Bacitracin in animal feed, the Community should have concentrated its efforts on banning the sale of antibiotics without prescription.

If Ladeur had analysed the cases more closely he would have seen that the Court anyway does not entirely reject the notion of relational rationality because it considers the problem of countervailing risks – whether, by eliminating one risk, the Community might have inadvertently caused other, possibly more significant, risks. So, for instance, it addresses Alpharma’s argument that the ban was aimed at a highly speculative risk to public health, but was likely to lead to more proven and significant risks because, firstly, a side-effect of Bacitracin is to strengthen chickens’ intestines, reducing the likelihood of them causing food poisoning if they rupture during processing, contaminating the meat with faecal bacteria, and, secondly, without regular dosing, animal infection rates are likely to rise in animals kept in confined spaces, which must then be treated with more powerful antibiotics than Bacitracin that are used more commonly in human medicine (research after the ban bore out this claim). As such, the Court essentially considers whether the ban creates more problems than it solved, making the cure worse than the disease, but, in the end, comes down on the side of the Community, accepting its explanation that these problems were more the result of intensive methods of farming than anything else and that they might be reduced with better animal husbandry and more hygienic farm conditions. The Court refers in particular to the Swedish experience with its ban on antibiotics as growth promoters, where although piglet mortality increased initially, requiring more antibiotics to treat infections, these ‘significant difficulties’ were eventually brought under control using deep straw bedding, improved hygiene and ventilation and by feeding chickens more fibre and less protein. The Court was unimpressed by Alpharma’s claim that little guidance could be drawn from the Swedish experience on the basis that its low animal population density was the real reason for the ease with which it had been able to bring infections under control after the ban. Nor was it persuaded by Alpharma’s argument that, even though doctors use Bacitracin to

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89 Pfizer, paragraphs 477-9.
90 ibid paragraph 419.
91 Alpharma, paragraphs 340-2.
93 ibid paragraphs 327-9.
94 ibid paragraphs 331-3.
95 ibid paragraphs 333-4.
treat human infections that had become resistant to other antibiotics, its use will remain rare and never become wide-spread because it damages the human kidney. It notes instead the ‘great importance’ of being able to rely on several different antibiotics to treat the same infection; the recent, dramatic increase in antibiotic resistance; the slowing rate at which new antibiotics are entering the market; and the fact that any increase in resistance ‘has significant long-term effects on public health, in that it is a virtually irreversible phenomenon’.

Taken together, these factors meant the Community institutions were entitled to adopt a precautionary approach whose objective was to preserve the maximum number of antibiotics effective in human medicine, even if they had never or rarely been used in this way. In particular, the Court, whilst acknowledging the ‘considerable scientific uncertainty’ and the absence of scientific proof for the theory of transferred resistance, notes that it is ‘corroborated by a certain amount of reliable scientific data’ and that there is a ‘very broad consensus among scientists’ that dual use antibiotics present the greatest risks.

In showing sensitivity to the context of the Community’s ban, the Court acknowledges that its institutions are entitled to take into account the fact that the citizens they represent are also far more sensitive to the context in which a risk arises than Ladeur’s highly reductionist approach would allow for. So, for instance, while any increased antibiotic resistance in humans, as a result of their use in animal feed, would be similar in nature (if not in degree) to that caused by their inappropriate use in human medicine, this does not mean the two practices can be measured on any linear scale. Attitudes to them can differ for perfectly rational reasons that have everything to do with the context. While Ladeur might dismiss it as inherently contradictory, it is not necessarily illogical to tolerate the well-documented increase in antibiotic resistance that is a consequence of easy, over-the-counter access to antibiotics to treat common infections (on the basis that this is more important to our general quality of life than safe-guarding the maximal-effectiveness of a few antibiotics used to treat more serious, but far rarer, infections) while at the same time refusing to countenance the unproven, and certainly smaller, risk associated with using antibiotics to artificially fatten pigs and poultry on the basis that you see no need to run the risk whatsoever. It is the pharmaceutical industry that cannot afford to wait for more research to be done on the risks. The rest of us can. Likewise, in rejecting a more recent challenge to the Community for infringing the principle of equal treatment, the Court refused to draw an analogy between the manufacturers of animal feeds, who must provide quantitative information as to their ingredients, and the manufacturers of food intended for human consumption, who need not, because:

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96 ibid paragraphs 42-4 and 273.
97 ibid paragraphs 251-5.
98 Pfizer, paragraphs 334-5, 338 and 442.
99 ibid paragraph 443 and Alpharma, paragraph 287.
100 Dir 2002/02
issue are not lawful on the ground of their discriminatory character. If that were not so, it would have the effect of bringing the level of public health protection down to that of the existing legislation which provides the least protection.101

And, when reviewing the Commission’s decision to reject a Danish request to maintain stricter limits on sulphite in food than the harmonised European standards, the Court considered the reduced technological need for the additive significant, which the Commission had asserted was irrelevant because all that was important was whether or not it was dangerous. As the Court puts it:

 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.102

However, although the Court defers a great deal to the Community institutions; accrediting them with considerable discretion to deal with the scientific advice as they see fit and therefore to give expression to our views about the acceptability or otherwise of various risk,103 possibly also sensing the potential for abused, it circumscribes this discretion by subjecting it to a range of counterbalancing procedural guarantees.104 Foremost amongst them is that the Community institutions should ‘carefully and impartially’ examine all the circumstances in

 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 … whose purpose is to ensure the scientific objectivity of the measure adopted and preclude any arbitrary measures.105

Additionally, it notes that all precautionary measures adopted in the absence of conclusive scientific evidence are provisional and there is therefore a duty to re-examine them in the light of fresh evidence, and that they must, in any case, be based on ‘as thorough a scientific risk assessment as possible’ as well as ‘the most recent results of international research’.106

Creating room to respond to popular voices

All in all, in Pfizer and Alpharma, the Court holds the Community institutions to their frequently-stated commitment to base their decisions on good science, elevating what might otherwise amount to little more than a hill of beans – an essentially empty promise

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101 Joined Cases C-453/03, 11-12/04 and 194/04, R v Secretary of State for Health, ex parte ABNA, not yet reported, paragraph 65.
102 Case C-3/00, Denmark v Commission [2003] ECR I-2643, paragraph 82.
103 Pfizer, paragraphs 166-170 and Alpharma, paragraphs 177-181.
104 Pfizer, paragraphs 387, 444 and 460 and Alpharma, paragraphs 318 and 355.
105 Pfizer, paragraphs 171-2 and Alpharma, paragraphs 182-3. The Court may well have emphasised these requirements due to their prominence in Article 6(2) of Regulation 178/02, enacted nine months earlier, setting up the Community’s flagship European Food Safety Authority.
106 Pfizer, paragraphs 158 and 162 and Alpharma, paragraphs 171 and 175.
– into some sort of obligation. At one extreme, the Court could enforce this as a procedural hoop, through which the Community institutions might easily jump, simply by consulting the Community’s scientists, regardless of whether they take a blind bit of notice of that advice, or, at the other extreme, it could exhaustively test regulations against that advice, which threatens to coalesce the scientific risk assessment and the political risk management. It would thereby elevate the scientific advice to a level at which it becomes \textit{de facto} binding on the Community’s institutions and pre-determines their regulatory decisions. Unsurprisingly, the Court falls somewhere between these two extremes, though its review does tend more towards the procedural than the substantive end, which would expose it to the sort of trans-scientific questions it is ill-equipped to answer.

There is a helpful parallel here with English criminal law, in which a defendant who wishes to rely on certain defences bears the evidential burden, which requires them to adduce sufficient evidence to make a particular defence a “live issue”, upon which the burden switches to the prosecution to prove the defence did not apply. In justifying a regulation aimed at a scientifically uncertain risk, the Community institution bears only the evidential burden, which it can discharge by pointing to some minimal scientific evidence that suggests a risk exists; whereas the challenger to that regulation, if it is to have any hope the Court will declare it illegal, bears the burden of proving that there was in fact no risk that required regulating, which it can only discharge if it proves this essentially to the criminal standard of beyond reasonable doubt. To this extent, Chalmers’ concern about the rigidity of the scientific constraints on the Community’s institutions is misplaced. His suggestion that they can avoid following the advice of the scientists only in ‘exceptional circumstances, where equivalent scientific evidence can be found and a justification for using it provided’ overstates the case.\textsuperscript{107} The Court has in fact set the evidential bar so low that the Community institutions should, in most cases, be able to make their regulations review-proof in spite of any “inconvenient” scientific advice.\textsuperscript{108} This is borne out by the fact that, time and again, the Court has emphasised the Community’s freedom to diverge from its scientists’ advice.

The Court distinguishes risk assessment, as an objective, scientific exercise, from the political exercise of deciding how to manage those risks; insisting that the Community conducts both when it regulates scientifically uncertain risks. The distinction serves the dual function of ensuring that political decisions are based on scientific facts, whilst retaining a proper degree of political autonomy \textit{vis-à-vis} those facts.\textsuperscript{109} So, although the Court recognises that there is an overlap as well as a complementarity between the two stages – they intertwine at different phases in the regulatory process\textsuperscript{110} – it is careful to caution against confusing them because they have distinct roles to play.\textsuperscript{111}

\textsuperscript{107} “‘Food for thought”: Reconciling European risks and traditional ways of life’ (2003) 66 MLR 532, 541.
\textsuperscript{109} N. de Saladeer ‘The precautionary principle in EC health and environmental law’ (2006) 12(2) ELJ 139, 147.
\textsuperscript{111} Pfizer, paragraph 149 and Alpharma, paragraph 162.
scientists as arbiters of fact who conduct risk assessments to identify and characterise risks and thereby generate reliable information – the raw factual data – upon which the Community institutions, as more legitimate arbiters of value, base the politically contentious dimensions of these decisions, whether they concern the appropriate level of protection or how to deal with uncertainty.\footnote{\textit{Pfizer}, paragraphs 159 and 172 and \textit{Alpharma}, paragraphs 172 and 211.} So, for the Court, the scientists provide ‘a reasoned analysis of the relevant facts of the case’, equipping the Community with ‘the factual knowledge which will enable it to take an informed decision’;\footnote{\textit{Pfizer}, paragraph 197.} whereas the Community institutions determine ‘the political objectives which they intend to pursue’; ‘the level of protection which they deem appropriate’ and they do so in the light of the level of risk they deem socially unacceptable, ‘above which it is necessary … to take preventive measures in spite of any existing scientific uncertainty’.\footnote{\textit{ibid} paragraphs 150-1 and \textit{Alpharma}, paragraphs 163-4. This is also the Commission’s view (COM/2000/1 final).}

The directives that set up the regulatory regime under which the antibiotics were banned frame the issues at stake in a narrow and purely scientific manner, requiring the Community institutions to exercise their regulatory power exclusively on the basis of a scientifically verified danger to public health.\footnote{Directives 70/524, 84/587 and 96/51.} But this sets out the issues differently from how they are understood by the public, which would largely prefer not to eat meat produced using antibiotics, regardless of the scientific evidence of any attendant risks. Particularly since the BSE crisis, there has been a deep rooted suspicion of industrialised agriculture in Europe. In this context, the public is not prepared to run any risk (no matter how minute or unproven) if it is unconvinced by the benefits of doing so. The Court therefore shows sensitivity to the political contention involved, which is apparent only when the risks are seen in their broader context and not pigeon-holed as being about whether the scientists tell us the practise endangers health or not. As such, the Court considers it appropriate to enlarge the Community institutions’ discretion in a way that reopens a space for them to respond to popular voices that the regulatory regime would have appeared to have closed off prematurely by focusing on scientific voices alone.

The Court is quite clear that the Community’s scientists possess ‘neither democratic legitimacy nor political responsibilities’, but only ‘scientific legitimacy’ and that this is ‘not a sufficient basis for the exercise of public authority’.\footnote{\textit{Pfizer}, paragraph 201.} This rules them out of taking the decisions involved in risk management, which the Court points out ‘necessarily entails political choices which can vary from one society to another according to the threshold of risk deemed acceptable’.\footnote{\textit{ibid} paragraph 447.} It points to various factors that potentially weigh in such decisions:

the severity of the impact on human health were the risk to occur, including the extent of possible adverse effects, the persistency or reversibility of those effects and the possibility of delayed effects.\footnote{\textit{ibid} paragraph 153 and \textit{Alpharma}, paragraph 166.}
And, when it comes to weighing the health risks associated with continuing to authorise antibiotics as growth promoters, whilst awaiting further scientific studies, against the primary benefits of doing so, which it notes are essentially about enabling the agricultural sector to operate more profitably,\textsuperscript{119} then, even if the ban makes it necessary to change farming methods to avoid too great a use of antibiotics and entails increasing production costs for farmers, it is nevertheless the case that the taking of such a measure is a matter for the community legislature.\textsuperscript{120}

And, in assessing the proportionality of that legislature’s decision, the Court takes into account the fact that antibiotics are not strictly necessary and that ‘there are alternative methods of husbandry even if they can lead to higher costs for farmers and, ultimately consumers’.\textsuperscript{121} This is surely correct because, ultimately, it is appropriate that a legislature should have the scope to respond to their constituents’ concerns about the use of antibiotics, especially as it is those constituents who pay for their risk-aversity with more expensive meat. It therefore lends the Council a ‘broad discretion’ to determine the objectives and factual base of its action and, ultimately, to decide the appropriate course, especially as it had to ‘assume its political responsibilities in the face of a particularly complex and delicate situation’ that involved ‘complex assessments of a scientific and technical nature’.\textsuperscript{122} Given that the Court can find no ‘manifest error’, it reassures the Council that it will not reassess the merits of the differing scientific opinions upon which it relied, or second-guess its decision by substituting it with the Court’s own,\textsuperscript{123} constantly repeating that it is only in a position to carry out a limited review.\textsuperscript{124}

So, although both sides put their scientific arguments to the Court at length, the Court did little to assess whose arguments were more convincing. It concentrated more on the evidence of a scientific debate than the quality of evidence put forward in that debate and used this to excuse itself from having to assess the merits of the arguments. For one lawyer, who has represented a number of pharmaceutical companies in challenges against the Community’s use of the precautionary principle, this amounts to a dereliction of duty because, although he accepts judges are better equipped to evaluate legal debates, we still deem them competent to decide all manner of complex issues in fields that go beyond their core expertise.\textsuperscript{125} The Court was too deferential and might, effectively, have decided without any scientific input at all, by concluding that as there was a scientific dispute, and as a certain weight of authority seemed to be in favour of a ban, a ban would be justified on the grounds of the precautionary principle, irrespective of the merits of the arguments advanced by the two sides.\textsuperscript{126}

\textsuperscript{119} Pfizer, paragraph 468 and Alpharma, paragraph 361.
\textsuperscript{120} Pfizer, paragraph 428.
\textsuperscript{121} ibid paragraph 459 and Alpharma, paragraph 354.
\textsuperscript{122} Pfizer, paragraph 443 and Alpharma, paragraph 349.
\textsuperscript{123} Pfizer, paragraph 166-9, 323 and 393 and Alpharma, paragraph 177-180 and 363.
\textsuperscript{125} {Forrester & Hanekamp 2005 #7360 /ft ": 306"}.
\textsuperscript{126} {Forrester & Hanekamp 2005 #7360 /ft ": 307"}. 

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And, whilst the Court accepts that the aim was not solely to create a favourable political impression that coincided with the prevailing public mood, it nevertheless considers the restoration of consumer confidence an appropriate objective in the circumstances, thereby implicitly authorising the Community to go beyond the scientific evidence when urged on by popular voices.

Though the Court did not use the argument, another reason for it finding that the Community’s decision was proportionate is that a softer form of regulation, like compulsory labelling that would have allowed individuals to exercise personal choice in their consumption habits, was ill-suited to the task because it is not individuals who develop resistance to antibiotics but bacteria. Consumers cannot protect themselves from the unproven (and in any case small) risk of transferred resistance by becoming vegetarian or buying organic meat because they are exposed also to infections from bacteria that have developed resistance elsewhere, including the possibility of transfer by way of those who continue to eat meat produced using antibiotics. Consumers cannot assume the risk at an individual level because others share the risks attendant on their personal choices. This makes it a classic free-rider problem, appropriately resolved by a collective decision as to whether or not it is worth it to us, as a society, to have cheap antibiotic-induced meat at the small risk of a further increase in antibiotic resistance and this is itself wrapped up with broader questions about the future of agriculture and whether we want our food to be produced using these sorts of industrial methods.

A deficiency in the Court’s reasoning?

Another way of considering the regulatory discretion that the Court extends to the Community institutions is to consider the issue from the opposite direction; from the point of view of a potential challenger to a Community measure and the difficulties that the Court puts in their way. When a measure’s scientific basis is at issue the Court effectively requires the Community institution that enacted it to put forward sufficient scientific evidence to make the risk it regulates a “live issue”, which requires the institution to do little more than put forward evidence of conflicting scientific opinions, some of which refuse to dismiss the existence of the risk entirely, upon which the Court is highly unlikely to overturn any measure that purports to deal with risk. Challenges are only likely to succeed if the challenger can present a virtually cast-iron case that there is no risk, essentially silencing all scientifically-qualified dissent. This is a tall-order. The Court, for instance, comes very close to demanding that Pfizer prove Virginiamycin is risk-free when it states that, although Pfizer had

admittedly, put forward a number of factors which could be advanced to counter the argument that there is a link between the use of Virginiamycin as an additive in feeding-stuffs and the development of streptogramin resistance in humans [it] does not claim that those arguments prove conclusively that there is no link … They merely demonstrate that

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127 Pfizer, paragraph 462.
the existence of such a link is ‘very unlikely’ and that other ‘plausible explanations’ existed.\textsuperscript{128}

This is effectively to require Pfizer to prove a negative. But, it is one thing to claim that a danger exists and a problem of quite a different order to prove that it does not.\textsuperscript{129} Pfizer can do no more prove that resistance has never transferred via the food-chain, than prove that it never will. It can show only that the likelihood is low. The Council can point to all the dire consequences should this happen. Whilst the Court’s oversight is curious when, earlier in its judgment, it shows that it is aware of the impossibility of proving a negative, stating that ‘a ‘zero risk’ does not exist, since it is not possible to prove scientifically that there is no current or future risk associated with the addition of antibiotics to feedingstuffs’,\textsuperscript{130} Forrester and Hanekamp tell only half the story when they describe this as a reversal of the burden of proof because it requires

those responsible for new scientific discoveries or new technologies to prove their achievements are not a potential source of risk, instead of requiring proof from those who allege they are.

In fact, they need do this only when they were unable to convince the Community to allow their discovery or technology in the first place, which it may well have done in spite of any risks, had it been persuaded of the benefits. As such, the heavy burden of proof falls only when they seek a second bite of the cherry and try to use the Court to force the Community’s hands. Generally, its institutions are better equipped than the Court to evaluate the various scientific and especially the popular voices that speak to what are commonly complex issues. So, in the absence of any serious error on their part, it is appropriate that the Court shows them considerable defence. As such, in these very special circumstances, it is appropriate that the Court comes close to requiring those who are responsible for a discovery or technology to prove it poses no risk before overruling a Community-imposed ban. The fundamental issue is before which forum such debates should be resolved – the Court that looks cold-bloodedly at the balance of scientific arguments, or the Community institutions that have the room to respond also to popular voices. Rather than being a dereliction of duty, the Court shows clearly that it understands both its limitations and its place in the Community’s constitutional order.

**Diet pills and food supplements**

Whilst Pfizer and Alpharma concerned the safety of antibiotics used to help animals gain weight, Artegodan, decided a couple of months later, concerned the safety of a diet pill used by humans to help them lose weight. On a narrow procedural point that turned on

\textsuperscript{128} ibid paragraphs 391-2.
\textsuperscript{129} It was Karl Popper, in *The logic of scientific discovery* (Hutchinson, 1959), who first demonstrated the impossibility of verifying the universality of a hypothesis in an open space, on the basis that it is impossible to cover all circumstances by induction (experience); making it possible always to claim that a hypothesis has not been investigated in a certain way and that therein lies its potential falsification. A hypothesis can neither be confirmed nor verified, but only corroborated.
\textsuperscript{130} Pfizer, paragraph 145 and Alpharma, paragraph 158.
the intricacies of the Community’s directive on the authorisation of pharmaceuticals,\textsuperscript{131} the Court of First Instance ruled that the Commission’s decision to withdraw authorisation of the diet pill had been illegal. It found that the Commission had acted outside its powers when reassessing the balance between the pill’s therapeutic benefits and its dangerous side-effects and this had been done to reflect a change in practice amongst doctors (who had come to favour a new, more effective diet pill carrying fewer dangerous side-effects, and generally live-style changes over pharmaceuticals as a means of tackling obesity) and not because any risk or lack of efficacy had been substantiated with ‘new, objective, scientific and/or medical data or information’ as the directive required.\textsuperscript{132} In sum, the Commission had changed its mind, not on the basis of any new information as to risks or lack of efficacy,\textsuperscript{133} but on the basis of a cross-comparison with a new pill, when the directive required it to balance only the therapeutic benefits (efficacy) and dangerous side-effects (risk) of each drug in isolation and authorise all those that pass this risk-efficacy threshold, thus leaving it to doctors to prescribe from a free choice of all those drugs that had cleared this hurdle to appear on the market. So, for instance, later that year, in \textit{Servier},\textsuperscript{134} the Court approved the Commission’s ban on two further diet pills because this time it was able to point to a new scientific study linking them with heart problems.

Though \textit{Artegodan} can be read narrowly, attributing the Court’s ruling to the intricacies of the directive at issue and the Commission’s failure to provide the form of justification required by the directive, it can also be subjected to a broader reading that emphasises both the novelty of the Court abandoning its usual deference towards the Commission’s handling of scientific evidence, as well as the unusual step it takes in commenting on (in what a common lawyer would understand as \textit{obiter dicta}) the substance of the Commission’s decision, even though this was not necessary to its decision because it considered the narrow procedural point sufficient to dispose of the matter.\textsuperscript{135} The Court effectively examines whether the science would have been sufficiently conclusive to justify the Commission’s decision, had it possessed the power it purported to exercise.

Speculating somewhat, the Court may have taken this step because it feared that it had recently shown itself to be a little too deferential towards the Community institutions on issues of scientific uncertainty and was keen to use \textit{Artegodan} to clarify its take on the precautionary principle and in particular to assuage fears, stoked by its judgments in \textit{Pfizer} and \textit{Alpharma}, that it would allow the Community’s institutions to plead the principle too easily to justify regulatory action without much in the way of supporting

\textsuperscript{131} Ar 11, Dir 65/65.
\textsuperscript{132} \textit{Artegodan}, paragraph 194.
\textsuperscript{133} The initial testing procedure for the diet pills had been extremely thorough and they had been monitored for between 12 and 35 years. Moreover, the scientific report the Committee for Proprietary Medicinal Products used to recommend a ban in 1999, on the basis that their efficacy was “likely to be insubstantial”, had persuaded it of their efficacy just three years before.
\textsuperscript{135} \textit{Artegodan}, paragraph 156. This was certainly the position of the Court of Justice, which was content to dismiss the Commission’s appeal on the basis that it agreed with the Court of First Instance on this narrow procedural point alone and therefore saw no need to pass further comment on the substance of the decision (Case C-39/03 P, \textit{Commission v Artegodan} [2003] ECR I-7885).
scientific evidence. The Court thereby fires a shot across their bows, warning them that its scrutiny is likely to be more searching than Pfizer and Alpharma might have led them to believe and also signalling that it will not be signing blank cheques for them to regulate with impunity simply by uttering the magic words “precautionary principle” whenever there is the merest hint of a scientifically uncertain risk.

The Court’s understanding of the precautionary principle in Pfizer and Alpharma follows the same lines as its depiction of the principle in National Farmers’ Union, in that it accepts that regulatory action may be justified even though a risk assessment has not provided ‘conclusive scientific evidence of the reality of the risk and the seriousness of the potential adverse effects were that risk to become a reality’ but, at the same time, ‘cannot properly be based on a purely hypothetical approach to the risk, founded on mere conjecture which has not been scientifically verified’. It uses Artegodan to further refine the principle; painting its scope of application in broad terms – so, even though the principle is found in the Treaty only in the Chapter on the Environment, the Court makes it abundantly clear that it is ‘autonomous’ and ‘general’ and applies unequivocally to all spheres of Community activity – whilst counterbalancing this with a signal that it intends to exert more control over the recourse policy-makers have to it in specific instances. In particular, it is more explicit about the amount of scientific evidence required to trigger the principle, which is what Manson refers to as the ‘knowledge condition’, and it demands ‘solid and convincing evidence which, while not resolving the scientific uncertainty, may reasonably raise doubts’. So, although it continues to permit Community institutions to respond to risks, ‘although the reality and extent thereof have not been ‘fully’ demonstrated by conclusive scientific evidence’, it still requires their response to be ‘adequately backed up by the scientific data available at the time’. Intriguingly, it also describes the principle as

requiring the competent authorities to take appropriate measures to prevent specific potential risks to public health, safety and the environment, by giving precedence to the requirements related to the protection of those interests over economic interests.

And it also requires public health protection to ‘unquestionably take precedence over economic considerations’. As such, it comes close to opening the door for the principle to be used as a “sword” by individuals seeking to challenge regulatory inaction (insufficient precaution) and thereby encourages them to have recourse to it to force the Community to behave more cautiously towards a given risk. This would be a significant step away from it being merely a “shield” that the Community institutions can call upon

137 Pfizer, paragraphs 143-4 and Alpharma, paragraphs 156-7.
138 Article 174(2) EC.
139 Artegodan, paragraph 184.
140 N. Manson ‘Formulating the precautionary principle’ (2002) 24(3) Environmental Ethics 263.
141 ibid paragraph 192.
142 Pfizer, paragraphs 142-4 and Alpharma, paragraphs 155-7.
143 Artegodan, paragraph 184 (author’s emphasis). See also Pfizer, paragraph 444.
144 Artegodan, paragraph 173. See also Article 152(1) EC Treaty.
to defend measures taken to combat scientifically uncertain risks that are challenged for being unnecessary, disproportionate, lacking in scientific justification, or otherwise inappropriate, which is the way the principle has traditionally been understood. 145

Some commentators unhelpfully collapse the precautionary principle’s incarnation as a non-judiciable guide to policy-making and its much narrower judiciable meaning. The Court had made it clear in Re Peralta that the Treaty obligation to base European environmental policy on the precautionary principle, 146 ‘confines itself to defining the general objectives of the Community in environmental matters’, 147 making it a guide to the Community’s exercise of its regulatory power and not a basis for a legal challenge in its own right. It confirmed this explicitly in National Farmers’ Union when it stated:

Where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent. 148

In this light, the potential new ground for judicial review that the Court appears to open up in Artegodan by using the word “requiring” in this context is likely to have been inadvertent. At least it seems unlikely that the Court would herald, with so little ceremony, the establishment of a judiciable standard that would be a prelude to a deep judicial incursion into the Community institutions’ regulatory power. And, even if the Court did realise its import and might countenance some sort of challenge to a Community institution’s failure to act against a risk in extreme circumstances, it would presumably only allow the principle to be used as a rather bluntish sword. A challenger would no doubt find it difficult to invoke to challenge total regulatory inaction and would likely have to wait to challenge the adequacy of some action, without which the Court would be in danger of straying too far into politically contentious territory; usurping the power of the Community institutions to determine regulatory policy for themselves. While the Court might be reasonably comfortable testing the adequacy of existing regulations against established legal principles, it would surely be uncomfortable defining appropriate regulatory policy from scratch, which allowing the precautionary principle to be used as a sword would bring it close to doing. As such, and despite the alternative interpretation that can be placed on Artegodan, the Court is likely to continue to see its role as limited to setting the parameters within which institutions can invoke the precautionary principle to defend themselves against challenges to the norms they have enacted.

As such, while Chalmers suggests the precautionary principle dictates that the ‘more pessimistic prognosis is to be acted on’, 149 this wrongly implies that it is a formula that dictates how institutions should exercise their regulatory powers when confronted by

145 The English High Court interpreted the principle in this way in R v Secretary of State for Trade and Industry, ex p Duddridge [1995] 3 CMLR 231.
146 Article 174(2) EC.
148 Case C-157/96, R v Ministry of Agriculture, Fisheries and Food, Commissioners of Customs & Excise ex p National Farmers’ Union [1998] ECR I-2211, paragraph 63 (author’s emphasis).
149 supra n?? at 543.
scientifically uncertain risks, when in fact it imposes no such obligation, but instead merely permits them to base their norms on some scientific evidence without having to wait for a risk to be confirmed by more definitive evidence. Similarly, Van Asselt and Vos claim the principle’s knowledge condition amounts to a demand that policy-makers appeal to scientists for some kind of plausibility proof or conclusive evidence as to whether or not something represents a risk, which is incompatible with or even flatly contradicts the notion of uncertainty that the principle responds to, which operates precisely when definitive proof or evidence is lacking.\textsuperscript{150}

Chalmers is however correct to point out that, although the precautionary principle regulates scientific disputes by lowering the threshold for the application of scientific reasoning when it cannot supply certainty, it applies only when some members of the scientific community raise the spectre of an uncertain risk and science must still guide the dispute. Regulatory decisions must continue to reference that scientific authority which is available, regardless of its uncertainty. Local, anecdotal knowledge, feelings of unease, superstitions and the like will not suffice, if they are not backed up by at least some scientific evidence, though this need not be particularly substantial. In \textit{National Farmers’ Union}, Advocate General Tesauro comes pretty close to the mark when he describes the trigger for the precautionary principle as ‘a real risk to human health which … no one has been able to rule out’.\textsuperscript{151} And, in \textit{Pfizer} and \textit{Alpharma}, the Court put it on record that minority scientific opinions can justify recourse to the principle provided they derive from scientific methods that have been agreed at international level or are recognised by a majority of scientists.

Commentators disagree on the quantity/quality of scientific evidence that must be adduced to defend a norm adopted with reference to the precautionary principle. Alternatives include: ‘plausible’;\textsuperscript{152} a ‘strong suspicion’ backed by ‘tentative and indicative scientific data’;\textsuperscript{153} or ‘a prima facie case’.\textsuperscript{154} But all these definitions are too linear. The scientific evidence required to trigger the principle must instead vary according to the nature of the risk, its likelihood and the potential magnitude of damage should it occur, as well as the reversibility of the damage. As such, the precautionary principle might be better seen as the principle of proportionality adapted to conditions of scientific uncertainty. The sensitivity of the trigger presumably depends on the nature of the risk and the potential magnitude of the consequences should it materialise – the merest scintilla of evidence that raises suspicion of potentially catastrophic consequences might suffice; whereas more concrete evidence of less significant consequences might not. Once the threshold is crossed, the policy-maker is \textit{prima facie} entitled to regulate, but the Court will still assess the proportionality of its action. However, the uncertain risk


\textsuperscript{151} Opinion delivered 30 September 1997, paragraph 22.


\textsuperscript{153} Jan ‘Objectives and principles of EC environmental law’ in G. Winter (ed), \textit{European environmental law: A comparative perspective} (Dartmouth, 1996) 277 at 284.

\textsuperscript{154} D. Freestone and E. Hey, \textit{The precautionary principle and international law: The challenge of implementation} (Kluwer, 1996) 32.
serves to de-intensify the stringency of this assessment, thereby extending latitude to it to respond to popular voices, provided they are backed by some (even if minimal) scientific evidence.

Significantly, the Court also uses *Artegodan* to signal its intention to reach further into the way the Community’s scientific committees operate. Although the Court reassures the Commission that it will not substitute its own opinion for that of the Community’s scientific committee, it does claim the right to review the committee’s ‘proper functioning’; the ‘internal consistency’ of its opinion; whether there is a comprehensible link between it and the scientific findings; and whether it provides a statement of reasons from which it is possible to ascertain the considerations on which it was based. It also requires the committee to refer to the main reports and scientific opinions upon which it relies and to explain, in the event of a significant discrepancy, the reasons why it departs from their conclusions – emphasising that this obligation is ‘particularly strict in cases of scientific uncertainty’.

When called upon to review highly-technical regulations, the Court confronts increasingly complex and compartmentalised science, which it has a limited capacity to grasp. It therefore focuses on policing the procedures by which regulations come into being, to ensure that institutions allow those parties that are scientifically and technically competent the opportunity to air their views and ensure those taking the ultimate decision properly consider them. It hopes thereby to proceduralise these arrangements to exploit the potential of scientific peer review – the quality control mechanism of the scientific community – so as to expose weaknesses in competing scientific theories, rather than try to do this directly, a task for which it is ill-equipped.

This extension of the Court’s jurisdiction to intensify its scrutiny of the way the Community’s scientific committees conduct themselves is particularly important in the light of the Community’s (and especially the Commission’s) favoured path of moving towards the use of (networked) regulatory agencies, like the European Food Safety Authority (EFSA), which will increasingly have risk assessment tasks assigned to them. *Artegodan* prepares the ground for these changes; a declaration of intent by the Court that gives it the wherewithal to extend its case law over these institutions, so that it might tweak their operation with legal principles, whenever it observes imperfections that it considers itself capable of correcting.

And again in 2005, in *Alliance for Natural Health*, the Court returned to the idea that it needed to get a handle on the Community’s scientific committees, through which so much regulatory policy at the European level is channelled (even if the final decisions are left to the Community institutions). In particular, it looked in detail at the procedures by which stakeholders might have their voices heard in communications between the Community institutions and the Community’s scientific experts.

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155 Committee for Proprietary Medicinal Products (now Standing Committee on Medicinal Products for Human Use).
156 *Artegodan*, paragraph 200.
157 *ibid.*
Trade associations, representing hundreds of generally small companies distributing dietary supplements in the UK challenged the validity of a Directive on food supplements that sought to remove barriers to trade caused by inconsistent national standards. It established a “positive list” system under which any food containing supplements could only be sold if those supplements had been designated as safe by the Commission, assisted by a comitology committee and the EFSA. Their challenge was based on the claim that the procedure to petition for inclusion on the list places a heavy financial and administrative burden upon their members, especially as it lacks transparency and precision as to the criteria the EFSA are to apply. The Advocate General agreed with their criticism and considered the Directive invalid because the prescribed procedure lacked transparency and legal certainty. However, the Court, which saw advantages in the “positive list” system (in contrast to a “negative list” system that the trade association favoured, but which would allow food onto the market that contained supplements never before subject to a scientific risk assessment) rescued the directive from these procedural imperfections by using the general principle of sound administration to go beyond its express terms and read into it an obligation, on the part of the Commission, to consult the EFSA transparently and within a reasonable time, as well as to ensure that the requirements to do so were ‘accessible’ (by which it means legally-enforceable) in that they were set out in binding measures of general application.

Though the principle of sound administration was well established, used in this bold fashion it may have far reaching implications for how the Court goes about developing its case law to correct imperfections it finds in the Community’s institutional structures.

**Conclusion**

Science is only capable of rationalising and thereby legitimising the Community’s regulatory power if the Community can determine how it is used by following what Habermas calls a ‘historically determined pre-understanding ... of what is practically necessary’, even as scientific voices question this pre-understanding in the light of new scientific possibilities for the gratification of practical needs, and this critical interaction must all the while be accompanied by the enlightenment of the political will, realised through articulation in public discussion at a pre-scientific level. The Community must hear, consider and respond to popular voices and their pre-scientific understandings and cannot just quote science back at the arguments they advance because the layman can characterise regulatory issues differently to a scientist without that categorisation being misconceived. The Community’s regulatory process must instead carefully blend what each of these voices has to say to it.

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158 Dir 02/46.
159 Standing Committee on the Food Chain and Animal Health.
161 *Alliance for Natural Health*, paragraphs 72-3.
The Court and its case law is crucial in setting the framework conditions that ensure the continuing vitality of interactions between popular and scientific voices within the Community’s regulatory process, in particular by marking out the functions of its various actors and consequently the channels through which these voices might feed into it. While the Court’s refinement of the part that science plays in legitimising regulation can be traced through a series of cases that extend back 25 years and which combine to proceduralise how the Community and its various agencies, committees and institutions go about regulating scientifically uncertain risks, its most impressive decisions have come in the last five years, when, amongst other things, it has:

(1) recognised science’s (partially justified) pretension to universality and fundamentally non-hierarchical character, which makes it appropriate that the Community examines all evidence, regardless of origin, and not just that supplied by the Community’s scientists;\footnote{Pfizer and Alpharma.}

(2) and carefully allocated authority between scientists, who are to provide reasoned factual analysis, and the Community institutions, which are to possess sufficient leeway to determine the Community’s political objectives in the light of these facts, as well as on the basis of what they considers to be a socially acceptable level of protection that is responsive to popular voices;\footnote{ibid.}

(3) refined the precautionary principle by emphasising the generality of its application, whilst requiring recourse to it be based on solid and convincing scientific evidence that, without resolving the scientific uncertainty, nevertheless raises reasonable doubts;\footnote{Artegodan.} and

(4) reached further into the way the Community’s scientific committees operate, to ensure their proper functioning and that they can demonstrate a comprehensible link between their opinions and the scientific reports and conclusions upon which they are based, which they may depart from as long as they explain why.\footnote{ibid and Alliance for Natural Health.}

Finally, and most recently, it referred to a principle of sound administration, when reading additional requirements into a regulatory procedure that revealed imperfections in the handling of scientific uncertainty,\footnote{Alliance for Natural Health.} and it is this principle that possibly offers the Court the greatest scope to go about regulating risk regulation because, with it, the Court carved out considerable room for itself to examine other procedures and ensure the Community hears, considers and responds appropriately to popular and scientific voices when regulating scientifically uncertain risks.

\footnotetext[164]{Pfizer and Alpharma.}
\footnotetext[165]{ibid.}
\footnotetext[166]{Artegodan.}
\footnotetext[167]{ibid and Alliance for Natural Health.}
\footnotetext[168]{Alliance for Natural Health.}