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In Ellen Vos, Michelle Everson and Joanne Scott (eds), *Uncertain Risks Regulated: National, EU and International Regulatory Models Compared* (UCL Press, Cavendish Publishing, Series: Law, Science and Society, forthcoming)

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OPENING PANDORA'S BOX: CONTEXTUALISING THE PRECAUTIONARY PRINCIPLE IN THE EUROPEAN UNION

Elizabeth Fisher[1]

Over the last decade the precautionary principle has become one of the most high-profile and contentious principles in European Union (EU) risk regulation and the principle has given rise to a burgeoning body of complex primary and secondary material as well as an overwhelming variety of arguments about its nature and validity.[2] In particular the principle has seemingly become a 'touchstone' for thinking about the challenges involved in regulating risk in a globalising world, concerning as it does both the internal and external exercise of state power (de Sadeleer 2002, Wiener and Rogers 2002). As this is the case the principle is an excellent, albeit daunting, starting point for thinking about, and comparing national, EU, and international regulatory models for risk standard setting.

My aim in this chapter is to examine a number of important issues for thinking about the precautionary principle in the EU and thus open up a Pandora's Box of issues for inquiry and debate. In the first section I give a brief overview of some of the key features of the precautionary principle including how the principle is a legal principle concerned with regulating the process of decision-making and how the principle's interpretation and operation will depend on legal culture (Fisher 2002). The second section analyses, from a conceptual perspective, the typical contexts the principle applies in and shows how the principle applies to both the internal and

external exercise of state administrative power. In both cases the operation of the principle raises issues of administrative constitutionalism, that is issues concerning how public administration should be constituted and limited to ensure it is legitimate (Fisher forthcoming). While how such issues manifest themselves is unique to a legal culture, there are also common understandings of administrative constitutionalism that can be seen in different jurisdictions.

The third section considers the operation of the precautionary principle in the EU. I show how there are at least six overlapping spheres of operation of the principle in the EU context. Considering these contexts side by side highlights: the pluralistic nature of administrative power and administrative constitutionalism in the EU; the fact that the same decision-makers are subject to different regimes of administrative constitutionalism; and that the operation of power in these different contexts is interdependent. In the fourth section I discuss the way in which widespread application of the European Commission's Communication on the Precautionary Principle (Commission of the European Communities 2000) has resulted in the promotion of a particular model of administrative constitutionalism and an assumption that one set of guidelines about the principle can apply in all the contexts the principle operates in. In the final section I discuss the tension that I see as inherent in the above discussion. On the one hand there is a need to recognise that how the principle is interpreted and applied is determined by legal culture and context. As such, there are limits to thinking in general terms about the principle and its implications for decision-making. On the other hand, there is an increasing tendency to characterise the precautionary principle in generic and almost functional terms as a principle that can be easily transplanted from one context to another.

Before starting I should stress that this chapter does not attempt to be a comprehensive account of the precautionary principle in the EU. For that readers will need to look elsewhere (Christoforou 2002, da Cruz Vilaca 2004, Scott 2004, Scott and Vos 2002).

THE PRECAUTIONARY PRINCIPLE AND THE IMPORTANCE OF CONTEXT

Before considering the principle in the EU context it is important to understand some basic features of the principle. The precautionary principle is a principle that is concerned with regulating the exercise of state regulatory power in relation to environmental and public health problems where collective knowledge of those problems is scientifically uncertain. The principle nearly always applies to standard setting and risk appraisal – that is the process of deciding whether to authorise a product or activity – and it primarily applies to public decision-makers.

Official histories of the precautionary principle identify its roots in West German environmental policy in the late 1970s and it then rising to international prominence in the late 1980s (Trouwborst 2002).[3] Such histories often assume linearity in the development of the principle while in reality the principle has been simultaneously developed in numerous different legal cultures (Fisher 2002). The precautionary principle was first included in Article 174(2) (then Article 130r(2)) of the EC Treaty in 1992 as a principle that Community environmental policy 'shall be based on'. However, before and after that date the principle, and associated ideas of precautionary action, were being developed by Community institutions in areas other than environmental policy[4] as well as by Member States (de Sadeleer 2000, Fisher 2001, Godard 2006, von Moltke 1988). This concurrent maturing of the principle has led to it having many different formulations. With that said the most common version

of it is that which has been developed in the international environmental law context. To paraphrase - where there is a threat to human health or environmental protection a lack of full scientific certainty should not be used as a reason to postpone measures that would prevent or minimise such a threat.[5]

Three basic features of the principle can be evidenced from this formulation. The first is that the principle is directly concerned with scientific uncertainty in environmental decision-making in that it states that 'lack of full scientific certainty should not be used as a reason' not to take measures. The complexity of scientific uncertainty and the problems it creates for 'factual' decision-making should not be underestimated (Wynne 1992). Scientific uncertainties arise in relation to risk regulation because of the ex ante nature of standard setting and risk appraisal, the need to operate on the basis of regulatory science not research science; and the fact that scientific knowledge in this area is plagued with methodological and epistemological problems (Dovers and Handmer 1999, Jasanoff 1990). Indeed the precautionary principle highlights the lack of ontological security in this area of public action and in particular the provisional nature of scientific knowledge (Jasanoff and Wynne 1998). Moreover, such scientific uncertainty tends to complicate other features of intractable environmental problems such as their polycentricity and socio-political ambiguity (Fuller 1978, Klinke and Renn 2002).

Second, the precautionary principle does not direct a particular outcome to occur. This is consistent with the status of the principle as a legal principle (Dworkin 1977, Fisher 2002) as well as with the fact that in circumstances of scientific uncertainty it would be illogical to talk in terms of outcomes (Mckinney and Hammer Hill 2000). Rather than being concerned with outcomes the principle regulates the way in which a decision is made, or in other words the decision-making *process*.[6] As

the principle is concerned with process it requires decision-makers to reflect on how they justify their decisions, what factors are relevant to a decision, how that decision should be made, and who should be involved in the decision-making process. In particular the principle is concerned with the reasons for a decision in that it states that in circumstances of scientific uncertainty a lack of certainty cannot be used as a reason for a decision.

Third, and following on from this the principle's operation will largely depend on the institutional and cultural context in which it operates. In particular, what is deemed to be an acceptable process pursuant to the principle will depend on normative understandings of good decision-making processes embedded in a specific institutional context. This means that the principle's operation is highly flexible, a fact again consistent with its status as a legal principle, and which can best be seen by the fact that the different 'operational' parts of the principle – the 'triggering threat', the basis of action, and the measures to be taken - are capable of differing definitions. Thus for example, a 'threat' can be defined: in quantitative terms as a certain level of risk; as a hazard; as a qualitative level of protection; and/or as a certain state of affairs that is deemed undesirable (Jaeger, et al. 2001, Stirling, et al. 2006). Moreover, as the principle gives negative guidance what is deemed as an acceptable course of action pursuant to the principle cannot only be determined by the principle alone but also requires reference to other factors.

From a cultural perspective, how the principle is interpreted and applied will depend on socio-political and legal culture (Fisher 2002). Roughly speaking, 'the idea of legal culture points to differences in the way that features of law are themselves embedded in larger frameworks of social structure and culture which constitute and reveal the place of law in society'.[7] Legal culture is particularly important as the

principle would never be found to require a process of decision-making that was irreconcilable with more general legal understandings of reasonable action within a jurisdiction (Fisher 2001). The important thing to appreciate here is that there is no universal formula for applying the precautionary principle just as there can be no formula for applying any other legal principle such as fundamental rights or proportionality (Deville and Harding 1997). While the principle requires decision-makers to focus on the problems of scientific uncertainty in decision-making, the actual nature of it will depend on the surrounding legal, institutional and socio-political context. As this is the case it comes as no surprise that the principle has given rise to diverse bodies of jurisprudence in different jurisdictions (de Sadeleer 2002, O'Riordan, Cameron and Jordan 2001).

From the scholar's perspective this may seem a little disheartening. Grand theories about precaution seem to dissipate into a series of culturally specific examples and attempts to draw comparisons and identify commonalities are hampered by the uniqueness of legal culture. Yet while legal culture is important it should not be emphasised at the cost of ignoring the fact that the precautionary principle, while taking on very different meanings, tends to operate in similar contexts in different jurisdictions. The next section considers those contexts.

CONTEXTS OF OPERATION

As already noted the principle is primarily a public law principle. In so being, it can apply to both the internal and external exercise of state authority (Fisher 2002, Godard 2006, MacCormick 1999). The principle's relevance in such contexts may be to: the design of the decision-making process, a particular decision, and/or to the process of holding the decision-maker to account through legal or some other type of proceedings. In this last regard, the application (or non-application) of the principle

may be subject to review and/or the principle may be a standard by which decisions are judged by.

Application to the Internal Exercise of State Sovereignty

From the internal perspective, the precautionary principle is a principle that governs what is understood as legitimate regulatory action in circumstances of scientific uncertainty. An overlooked feature of such action is that it is invariably administrative in form due to the resource intensive nature of standard setting and risk appraisal (Fisher forthcoming, Fisher and Harding 2006).[8] These activities require the collection and evaluation of large amounts of information, the identification and consideration of expert opinion, the communication between numerous different actors, and the application of legislative prescriptions to specific complex circumstances. In a conventional separation of powers context, neither an elected body nor a court can provide an adequate forum for these activities to take place (Fisher forthcoming).

Stressing the administrative nature of standard setting and risk appraisal and thus of the principle's application is not mere pedantry on my part. It is essential in understanding the nature of the principle and the challenges involved in its application. As already noted, what is understood to be a legitimate interpretation and application of the principle will depend on context. As that context is public administration then the principle must be understood against the background of understandings about the role and nature of public administration. Indeed, one of the reasons why the principle is so contentious is because in removing 'the facts' as a reason for a decision the principle is seen by some as an excuse for arbitrary administrative decision-making because a factual basis has been a conventional way of ensuring the accountability of public administration (Marchant and Mossman 2004,

Sunstein 2005). For others, however, the principle promotes good public administration because the principle allows for a more reflexive and pluralistic administrative process that takes into account the complexity of decision-making in this area (Klinke and Renn 2002, Stirling 2001).

Indeed, what different perspectives on the principle highlights is that there is very little agreement about public administration. Administrative bodies occupy a necessary but awkward space in liberal democracies and there is a considerable polarization of views over what the nature and form of legitimate public administration is and should be (Cook 1996, Mashaw 2002). This is particularly the case in relation to risk regulation because standard setting in this area requires delegation of large amounts of discretionary authority to public administration in circumstances of scientific uncertainty and socio-political conflict over the role of the state (Douglas and Wildasky 1982). As a legal principle, and like all law in this area, the precautionary principle is integral to the process of constituting decision-makers, limiting their powers, and holding them to account. As such, legal debate will often be about whether a particular interpretation of the principle accords with understandings of the role and nature of public administration (Fisher and Harding 2006).

These debates are debates over administrative constitutionalism in that they are normative debates over what the role of law should be in ensuring legitimate administrative governance (Fisher forthcoming). Moreover, because of the contested nature of public administration debates over administrative constitutionalism are ongoing as legal actors are constantly questioning and challenging the role and nature of administration (Fisher forthcoming). Understandings of administrative constitutionalism are unique to a particular legal culture but at the same time there are basic normative understandings about the role and nature of public administration that

are common across most jurisdictions. In particular, two paradigms of administrative constitutionalism have tended to dominate risk regulation – the deliberative-constitutive and the rational-instrumental (Fisher forthcoming). The former characterises the role of public administration in flexible and discretionary terms while the latter understands the role of public administration more as a Weberian agent of the legislature which a specific set of tasks. Each of these paradigms have their benefits and drawbacks and the simultaneous operation of them in most jurisdictions is arguably a desirable state of affairs as it reflects the difficult role of public administration in the risk regulation context.

This close interrelationship between the precautionary principle and administrative constitutionalism means that how the principle is defined, applied, and decision-making pursuant to it subjected to review, will depend on ideas of administrative constitutionalism. This is in two ways. First, these different paradigms will influence how the precautionary principle is interpreted and operationalised and as I have shown elsewhere the precautionary principle can be interpreted in deliberative-constitutive or rational-instrumental terms (Fisher forthcoming, Fisher and Harding 2006). Second, at the same time, the precautionary principle has tended to be more commonly characterized as promoting a deliberative-constitutive understanding of public administration because it requires a more flexible and less rule-bound approach to public decision-making. Indeed, rational-instrumental understandings of the precautionary principle appear more strained and less logical than deliberative constitutive understandings because inherent in them is a paradox – rational instrumental public administration ideally acts on a factual basis but the precautionary principle highlights the problems with relying on a factual such a basis in circumstances of scientific uncertainty.[9] All in all, debates over the principle are in

essence a continuation of debates over the role and nature of public administration. Whether the principle is accepted as valid, or how the principle is interpreted, will result in one paradigm being promoted over another.

It is also worth noting a number of other consequences of understanding the principle in terms of administrative constitutionalism. One is that the principle's operation does not involve a crude choice between democracy or science as some commentators have suggested (Morris 2000, Sunstein 2005) – all standard setting administrative regimes will draw on both science and democracy but the differences will be in how these terms are defined and how science and democracy are understood to interrelate (Fisher forthcoming). Likewise, the populist shorthand for describing the precautionary principle as a 'shifting of the burden of proof' is a misconceived one. Burdens of proof are relevant to the evidentiary responsibility of parties in a courtroom and not to the legitimate exercise of administrative power (Fisher 2001).[10]

External Exercise of State Sovereignty

The precautionary principle does not only relate to exercises of internal state authority however, but also to the exercise of external state authority. This may be relevant to how a state operates in an international, trans-national, or supranational context. In these circumstances the principle acts as a reason to require sovereign states to take action (Cameron and Abouchar 1991, Trouwborst 2002) or acts as a reason for a state to derogate from their international obligations (Bohanes 2002).[11] Obligations that fall into the former category have invariably taken a soft law form outside the supranational context and have tended to be considered in the context of international environmental regime building (Scott 2001). Examples that fall into the latter category have had the higher profile and been the subject of more commentary (Bohanes 2002, Button 2004, Perez 2004).

In each case the precautionary principle needs to be interpreted in light of the framework of legal obligations, the purpose of such regimes, and the legal culture. As with the exercise of internal state authority there is likely to be profound disagreements over what is the purpose and nature of legal provisions and this will be reflected in legal frameworks and dispute resolution processes. Thus for example in the EU setting, there has been an evolution in the jurisprudence over the fundamental freedoms which has resulted in not only a metamorphosis in understanding what is the nature of such freedoms but also when is it legitimate for a state to derogate from their trade obligations (Barnard 2004). Likewise, it is not clear whether the World Trade Organisation (WTO) Sanitary and PhytoSanitary (SPS) Agreement is either an elaboration of what is understood to be unjustifiable discrimination or a more ambitious regime designed to minimise regulatory heterogeneity (Fisher forthcoming). In all cases a variation in what is understood to be the purpose of trade obligations will result in a variation in how the precautionary principle is defined and assessed.

While the ways in which the precautionary principle operates in the internal and external spheres are theoretically distinct there is a very close conceptual relationship between the two. It is close in two senses. First, the same institutions are nearly always being used for the internal and external exercise of state authority. This is particularly the case in an era in which non-discriminatory risk regulation measures are subject to trade obligations due to the fact that national risk regulation standards prima facie will be the subject of trade obligations.[12] Second, and adding more complexity to the matter, what is a ‘reasonable’ exercise of external state authority will involve a determination of what is an appropriate model of administrative constitutionalism to be operating in that context (Fisher forthcoming). This is because

in deciding what is a 'reasonable derogation' reference must not only be had to the purposes of trade regimes, but also to common understandings about how risk regulation standards are set. As risk regulation standard setting is administrative, implicit in those common understandings are understandings of administrative constitutionalism. This is obvious when one turns to commentary that discusses whether a state can utilise the principle in derogating from their trade obligations. Whether a commentator thinks a state can or not depends on what that commentator thinks is rational and non-arbitrary decision-making which in turn depends on principles of administrative constitutionalism (Bohanes 2002, Majone 2002, McNelis 2000).

This relationship between trade law and administrative constitutionalism has not been commonly recognised (Fisher forthcoming) and it is useful here to briefly elaborate on this point in the EU context to show the importance of it. Over the last thirty years the European Court of Justice (ECJ) has produced a complex body of case law concerning what is the nature of the free movement of goods obligation under Article 28 and when a Member State can derogate from that obligation. Maduro has argued that this case law is an example of the European Court of Justice (ECJ) engaging in economic constitution building and the Court has encouraged Member States to harmonise their regulatory approaches (Maduro 1998). This thesis is undoubtedly correct but the problem is, as he explicitly notes, the case law concerning Member State risk regulation measures does not fit his thesis. This is because his thesis concerns the harmonisation of regulatory outcomes and in the risk regulation cases the Court has allowed a proliferation of different regulatory outcomes, much so than in other areas.[13] Yet if one looks at the cases that do not conform to Maduro's thesis through the lens of administrative constitutionalism one can see that while

Maduro's thesis is correct his focus is wrong. In the risk regulation cases it is not outcomes which the Court is harmonising but ideas of administrative constitutionalism. In these cases the Court is scrutinising carefully the process by which risk regulations are set and assessing those processes against commonly understood ideas of administrative constitutionalism in the EU context. The focus of the Court in these decisions is upon the process of decision-making – the reasons for the decision, who the state consulted, the information they relied on, and so on – to establish whether the state was exercising their power reasonably (Fisher forthcoming).[14] Moreover, in making that determination the Court is clearly influenced by how similar decisions are being made in other Member States and at the Community level.[15] In other words, the Court's 'majoritarian' approach is in harmonising what is understood as 'reasonable' administrative process on the part of Member States, taking into account ideas of administrative constitutionalism that exist in Member States and the Community.

THE PRECAUTIONARY PRINCIPLE IN THE EU

The discussion so far has highlighted the fact that while each example of the precautionary principle is dependent on context and legal culture, there are common themes that arise in the principle's application, in particular that of administrative constitutionalism. When one turns to the EU context one can begin to see the importance of culture, context, and administrative constitutionalism. This is best evidenced by applying the internal/external authority schemata above to the precautionary principle's application in the EU. When one does this, at least six overlapping spheres of operation of the precautionary principle can be identified (Fisher 2002). These are:

a) *The application by Community institutions in carrying out their international obligations*. This may include where the principle is being used to reinforce those obligations[16] or, more controversially, where the principle is being used to derogate from those obligations.[17] In most cases, such decisions will actually be exercises of internal Community power and thus the decisions will be of committees, agencies, the Commission, Parliament and the Council. In determining what is 'reasonable state action', however the context is an external one and regulated by international agreements.[18]

b) *The application by Community institutions in exercising their power pursuant to a Community regulatory regime*. Community institutions may rely on the principle in the creating of a new legislative/regulatory scheme[19] and/or in the exercise of power in relation to a specific product or activity.[20] The principle may be utilised by a range of different institutions including the Commission, committees and agencies but because of the rules concerning delegation in the EU these decisions will nearly always be attributed to the Council.[21]

c) *The application of the principle by Member States when operating pursuant to Community regulatory regimes or competence.* The principle may be relevant to how Member State authorities choose to interpret a directive[22] and to the type of discretion that they have pursuant to that directive.[23] At the Member State level, application will be by national administrators or by courts drawing on national and EU legal principles.[24]

d) *The application of the principle by Member States where there is a Community regulatory regime but a Member State wishes to rely on the principle in derogating from the obligations of that regime*. This may involve cases where

the Member State is relying on specific provisions of a directive or regulation[25] or provisions of the Treaty such as Articles 95(4) and 176.[26]

e) *The application of the principle by Member States where there is no Community regulatory regime but application prima facie infringes other Community obligations*. The most obvious example here is where such application prima facie infringes Article 28.[27] The legal question which arises is whether a Member State is justified in taking such action under either Article 30 TEC or the *Cassis* mandatory requirements doctrine.[28] In such cases a Member State must establish that their prohibitions of restrictions shall not 'constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States'.[29] Broadly speaking this requires a Member State to establish that the measure is necessary, appropriate and proportional.

f) *The application of the principle by Member States in matters with no relationship to EU law*. This will include areas such as town planning and will often be in the context of well entrenched statutory regimes.[30]

Four important features of the application of the precautionary principle in the EU are apparent from this list.

First, it is clear that a diverse range of administrative institutions operating at the national and Community level are involved in the application of the precautionary principle. These institutions include: a network of national administrations; panoply of different types of committees; the European Commission; and a range of Community agencies.[31] This is even the case where the Council is vested with the formal role of passing risk regulation standards. These institutions take many different forms and will be operating in different legal cultures. From the perspective of thinking about

the precautionary principle the range of different institutions means that there will be a range of different legal contexts that the principle is applying in. At the national level these contexts are relatively conventional, albeit controversial. The same is not true in relation to the Community level and care needs to be taken with the concept of 'administration', particularly as the EU is a polity that does not conform to the separation of powers doctrine. Rather institutional development has adhered (although not always strictly) to the very different ideal of institutional balance (both in its horizontal and vertical sense) (Prechal 1998), which has little room for the growth of an administrative arm of EU governance.[32] I use the term 'administrative' here to refer to institutions that have had their tasks delegated to them from a primary decision-maker.

Second, and following on from this, how the principle is applied and interpreted will be influenced by debates over administrative constitutionalism operating in each specific context and legal culture (Fisher 2005, Fisher and Harding 2006). Some of those debates will be occurring at the national level, some at the Community level, and some involving both. Those with a Community aspect are particularly complex because of the *sui generis* nature of the EU and the fact that there is no agreement over what is EU administrative space. Recent discourses over comitology and the role of other committees are a good example of this (European Institute of Public Administration 2000, Joerges and Vos 2000) but the same is true in relation to the role of national administration in both implementing and participating in EU regulatory schemes (Demmke and Unfried 2001).[33] Moreover, in many cases that debate has been hampered by a lack of basic information about such institutions which has only begun to be remedied in the last several years (Vos 1999). Debates over administrative constitutionalism have also overlapped with more general debates

over constitutionalism, a fact due to the non-elected nature of most Community institutions (Bignami 1999, Joerges, et al. 2002, Lindseth 1999).

From the perspective of the precautionary principle, what all this means is that it is absurd to expect consistent interpretation and application of the principle. This is in two senses. In the first sense, it means that in any particular context there will be debates over what are the appropriate understandings of administrative constitutionalism to apply to that context. In other words, whether decision-making should be on the basis of the deliberative-constitutive or rational instrumental paradigm. Thus for example, as will be seen below, whether the European Commission's Communication on the Precautionary Principle (Commission of the European Communities 2000) is seen to be valid or not has depended on whether the rational-instrumental paradigm of administrative constitutionalism it promotes in the Community context is viewed as valid. Likewise, differing interpretations of what is understood by 'risk assessment' under the WTO SPS Agreement are dependent on what model of administrative constitutionalism is relied on in interpreting that Agreement.[34] Thus for example in *EC-Hormones* the Panel interpreted the Agreement in rational-instrumental terms while the Appellate Body interpreted it in deliberative-constitutive terms (Fisher forthcoming).[35] The second sense in which it is improper to expect a consistent interpretation of the precautionary principle is that the nature of debates over administrative constitutionalism will vary from context to context. Thus for example, the type of unilateral action held to be reasonable for a Member State to take when there is no harmonised scheme, and when there is one, are clearly different categories - the latter one being shaped by the recognition of the importance of co-operation between all Member State administrations and Community administration.[36] Moreover, and looking more widely, the ECJ has developed a very different

jurisprudence over the validity of Community precautionary action as compared to that concerning when it is valid for a Member State to derogate from their Article 28 obligations. In the former category the Court's approach has been shaped by emerging understandings about the role and nature of Community institutions and the role of judicial review in holding them to account.[37] In the latter category the Court's jurisprudence is a product of understandings about the nature of Article 28, harmonised regimes, and understandings of administrative constitutionalism common among Member States.[38]

Third, there is clearly an institutional overlap between these different categories with only category f) artificially not doing so.[39] In other words, the same institution can find themselves subject to two different discourses over administrative constitutionalism operating in different legal cultures. Thus for example categories a) and b) will nearly always overlap as they did when the EU banned the use certain growth hormones in beef cattle.[40] In that case, the SPS regime required the decision-makers to base their measure on a risk assessment, albeit not defining what that meant, while the EU framework did not. A similar problem of overlapping discourses of administrative constitutionalism can also be seen in regards to cases falling into category e).[41] Thus for example in *Toolex Alpha* a decision by Sweden to ban a certain chemical was entirely consistent with the principles of administrative constitutionalism operating in that legal culture. The question for the ECJ however, was whether Sweden's regulatory action was consistent with what were understood to be as valid administrative constitutionalism norms for Member States to rely on in derogating from Article 28.[42] Moreover, those that fall into categories c) and d) are particularly problematic because it is not obvious what the analytical starting point should be (Bignami 2004). Should these be considered as examples of the exercise of

Member State external sovereign authority or as examples of the internal exercise of authority pursuant to a statutory regime? In all these cases, ideas of administrative constitutionalism will be drawn from a range of national, supranational and transnational sources.[43]

Fourth, and following on from this, there is also a close interrelation between these different exercises of administrative power. Thus for example, because the exercise of Community power in this area is so heavily dependent on the operation of comitology committees it means that Community administrative action often has as its impetus Member State action.[44] Likewise, because many regulatory regimes are in the form of shared administration they require the concurrent exercise of administrative power by different Member States and Community institutions.[45] Take for example, the decision-making processes which were subject to review in *Pfizer*,[46] one of the first CFI decisions which examined the principle. The case concerned a regulation that banned the use of certain antibiotics in animal feedingstuffs because of the potential but unproven risk that such use may lead to antibiotic resistance in humans. The regulation was the result of a decision-making process under Directive 70/524/EEC concerning additives in feedingstuffs.[47] The process was begun by Denmark (followed later by other Member States) exercising its right to apply a safeguard clause under Article 11 of that Directive by putting forward a dossier to the Standing Committing on Animal Feedingstuffs, a comitology committee.[48] Further information was collected, the Scientific Committee on Animal Nutrition was consulted, and ultimately the Standing Committee voted on the measure. What can thus be seen is that the ultimate regulation was the product of decision-making by a series of interrelated administrative institutions. This is even more the case when one considers

the different institutions which were also involved in identifying antibiotic resistance as a problem.[49]

What all the above highlights is that it is very difficult to make generalisations about how the precautionary principle operates in the EU. There are too many administrative contexts and too many different debates over administrative constitutionalism for that to be the case. At the same time, however, there are a series of overlaps and interdependencies between different administrative institutions. The problem is that while once there was some appreciation of these complexities this would no longer seem to be the case. This is the focus of the next section.

THE EUROPEAN COMMISSION'S COMMUNICATION ON THE PRECAUTIONARY PRINCIPLE

Throughout the 1990s the principle and associated ideas of precaution were relied on by both the Community and Member States but rarely was there any detailed discussion of the principle and its consequences. With that said, a complex body of jurisprudence was developed by the CFI and ECJ in relation to when and on what basis various categories of precautionary action were valid (Scott and Vos 2002). What is clear from that body of case law is that understandings of reasonable administrative action were being shaped by a range of different factors including norms of administrative constitutionalism.[50] Indeed, a clear difference in approach can be seen in how the ECJ considered and analysed precautionary action in the different contexts.[51] With that said it is interesting to note that while the validity of action would depend on context, the courts particularly when reviewing the validity of Member State action, were clearly being affected by the policy and administrative constitutionalism norms promoted by Community regulatory regimes.[52] There were however no universal requirements for a risk assessment although a careful scrutiny

of information by the decision-maker was required.[53] In this regard it is useful to remember that risk assessment, is itself largely a product of regulatory politics (Fisher 2006, Jasanoff 1986).

By the end of the 1990s there was an increased perception of a need for there to be more authoritative guidance about the nature of the precautionary principle, what it entailed, and when it could be applied. In February 2000 the European Commission published a Communication in which they outlined how *they* would apply the principle. The Communication was silent on which contexts they were planning to use it in but clearly the Commission's concern was to explain how administrative power would be exercised in categories a) and b). First, the Communication was explicitly designed to show that EU decision-making pursuant to the precautionary principle was consistent with how the WTO SPS Agreement had been interpreted in WTO dispute settlement proceedings (Majone 2005).[54] The second purpose of the Communication was to promote the 'accountability' of Commission decision-making, something that was seen of mounting importance in light of Commission corruption scandals (Craig 2000), the controversy over the Community's action in relation to BSE (Chambers 1999), new empirical insights into Community decision-making (Vos 1999) as well as the growing obviousness of a democratic deficit (Weiler 1999). Moreover, there was an increasing interest in delineating the 'administrative' institutions of Community governance and constituting and controlling their power accordingly (Bignami 1999, Craig 1997, Majone 2002, Vos 2000). In this regard, the Commission's Communication should be seen in the context of a number of other Commission documents at that time which had as their concern the regulating of 'administrative' decision-making within the Community

(Commission of the European Communities 2000, Commission of the European Communities 2001, Commission of the European Communities 2002).

It is useful to briefly outline the main features of the Communication guidelines. In the Communication standard setting and risk appraisal are understood to involve a scientific process of risk assessment; a political process of risk management; and risk communication.[55] Theoretically, the Communication relates to risk management but the principle only applies when a risk assessment has identified a 'potential risk' and the uncertainties surrounding it. When a risk assessment does identify a potential 'negative effect' after a scientific evaluation has been done then, as part of risk management, there must be a decision to act or not to act and the precautionary principle will directly apply to this. In deciding this question, the Communication stresses the need for there to be an assessment of the uncertainties involved in the evaluation, and an assessment of the possible consequences of inaction, or waiting for more scientific information. The process of applying the principle must be transparent and inclusive, particularly in assessing the consequences of different forms of action and inaction. The Communication, however, describes this as a 'political decision' and provides few guidelines for this process of evaluation. What the Communication does do, however, is set out a series of standards by which the measures to be taken must be judged. Any measures taken pursuant to the principle must be proportional, non-discriminatory, consistent, based on an examination of potential costs and benefits, subject to revision in light of new data, and capable of assigning responsibility for the production of more scientific evidence.

I wish to note two features of the principle here, both of which I consider together below. First, the Communication is promoting a rational-instrumental

understanding of the precautionary principle. Second, the Communication has been understood as a set of universal guidelines that can apply to all contexts.

The Communication is a perfect example of how the precautionary principle is concerned with regulating the process of decision-making on the basis of a particular model of administrative constitutionalism. The Communication is based on a 'rational instrumental' model and, as such, its guidelines are a good example of the problems of trying to apply precaution in a regime that defines a valid decision as a factual one (Fisher and Harding 2006). Likewise, the responses to the Communication were very much in terms of whether it promoted the model of public administration that the responder deemed valid (Majone 2002, Sunstein 2005). Graham and Hsia praised the Communication for the orderly process it created which 'requires the kind of formal policy analysis' taught in 'schools of public policy and public administration' while also criticising it for allowing the unchecked exercise of discretion (Graham and Hsia 2002). The European Council published a resolution in reply to the Communication in which they broadly agreed with it although they placed greater stress on the importance of deliberation and the role of values, thus arguably a more deliberative-constitutive approach to standard setting (European Council 2000). A similar type of response could also be seen from the Committee on the Environment, Public Health and Consumer Policy of the European Parliament (Committee on the Environment Public Health and Consumer Policy of the European Parliament 2000). In all cases the focus was on whether the Communication would aid 'rational' decision-making where what was understood as 'rational' was defined in accordance with understandings of administrative constitutionalism.

In 2001 the Communication clearly influenced a European Free Trade Association Court case concerning whether Norway was justified in banning vitamin

and iron enriched cornflakes.[56] The Communication was not cited in the case but the Commission was a party and the Court's description of legitimate action pursuant to the precautionary principle paraphrased the Communication. The first substantive EU case law in which the precautionary principle was considered was in 2002 by the CFI in *Pfizer* and *Alpharma*, the former being discussed above.[57] The Court in two lengthy judgments upheld the regulation. There is no room here to go into the details of those decisions but there are two important things to note. First, the cases were primarily concerned with the CFI's review of the process of decision-making and the consideration of the legal arguments in relation to the precautionary principle overlapped with legal arguments in relation to procedural impropriety, proportionality and manifest error of assessment. The decision is thus a good example of how the principle raises issues of process and administrative constitutionalism. Second, in considering whether there had been a proper application of the precautionary principle the CFI adhered to the Communication guidelines in their interpretation of the precautionary principle even though the Communication had not been published at the time the Regulation had been passed. After a lengthy and not always straightforward analysis of the principle the CFI stated:

> So, where experts carry out a scientific risk assessment, the competent public authority must be given sufficiently reliable and cogent information to allow it to understand the ramifications of the scientific question raised and decide upon a policy in full knowledge of the facts. Consequently, if it is not to adopt arbitrary measures, which cannot in any circumstances be rendered legitimate by the precautionary principle, the competent public authority must ensure that any measures that it takes, even preventive measures, are based on as thorough a scientific risk assessment as possible, account being taken of the particular circumstances of the case at issue. Notwithstanding the existing

> scientific uncertainty, the scientific risk assessment must enable the competent public authority to ascertain, on the basis of the best available scientific data and the most recent results of international research, whether matters have gone beyond the level of risk that it deems acceptable for ……. That is the basis on which the authority must decide whether preventive measures are called for.
>
> Furthermore, a scientific risk assessment must also enable the competent authority to decide, in relation to risk management, which measures appear to it to be appropriate and necessary to prevent the risk from materialising.[58]

This statement paraphrases much of the logic of the Communication. One can also see that there is a real tension in this statement between requiring a decision-maker to base their decision on the facts and for them act on other grounds in circumstances of scientific uncertainty (Fisher and Harding 2006, Lee 2005).[59] That tension makes the guidelines problematic to the point of being unworkable (Fisher 2006).

Despite these problems in the guidelines they, and the interpretation they have been given by the Court, have been the basis for the ECJ and CFI assessing the validity of precautionary action and the application of the precautionary principle ever since.[60] In particular the CFI and ECJ have required those bodies under review to carry out as thorough a risk assessment as possible before applying the precautionary principle. The Communication has been used as the basis for assessing the validity of decision-making in categories c),[61] d),[62] e)[63] and even f)[64] as well as being argued in relation to Article 230 (category b) cases).[65] Likewise, the ECJ's past case law has been re-interpreted as being consistent with the Commission's guidelines, even though those cases arguably promote a deliberative constitutive not rational instrumental understanding of administrative constitutionalism.[66] There has been little

discussion about the relevance or appropriateness of the Communication guidelines being applied to these different contexts. Moreover, a certain pedantry can be seen in the application of the guidelines and there have been a number of cases in which the principle has not been found to apply because the principle should only apply: to provisional risk management measures;[67] where there is a something more than a 'hypothetical' risk;[68] where there is scientific, as opposed to other types of, uncertainty,[69] and not to cases where the risk is well known.[70] Indeed, it would seem that the principle is being treated more as a 'bright line' rule which dictates certain action in particular situations rather than a flexible principle that might result in a variety of outcomes.

Moreover, in discussing EU risk regulation there has been three tendencies which are a product of the current approach to thinking about the precautionary principle. First, the precautionary principle has become synonymous with risk assessment even though the relationship between the two is a product of the SPS Agreement and the promotion of a rational-instrumental paradigm (Fisher 2006, Fisher and Harding 2006). There has been little recognition of the fact that risk assessment is a flexible regulatory construct or that the principle may operate separate from risk management. Second, the precautionary principle has been treated as short hand for describing the whole of European risk regulation (Kogan 2005, Wiener and Rogers 2002). The principle is described as a 'central guideline' of EU consumer policy (Strünck 2005) and there seems little appreciation that the principle may have different meanings. Third, and following on from this, there appears to be little appreciation in some quarters that the principle is operating in different contexts and that this will result in different interpretations of the principle and different outcomes (Marchant and Mossman 2004, Sunstein 2005). Indeed the variation of definition is

largely seen as a weakness of the principle rather than reflecting its context bound nature.

All of the above is somewhat ironic. While the Commission described their Communication as a contribution to the 'ongoing' debate the result of its publication has been to silence that debate (Commission of the European Communities 2000). The principle has become a set of fixed rules and as such has required decision-makers to apply a rigid framework for decision-making rather than adapting their decision-making process to the problem at hand. There has been a shift away from thinking about the reasonableness of administrative process and rationality to thinking in terms of a formula. This is particularly odd when the Communication is not particularly logical and the ECJ and the CFI are increasingly discussing principles of administrative constitutionalism while reviewing complex administrative decision-making in areas where the principle is not being applied.[71]

OPENING PANDORA'S BOX

What all of the above highlights is that there is, at present, an inherent tension in thinking about the role of the precautionary principle in EU risk regulation. This tension is between recognising the context- and culture- bound nature of the precautionary principle and of the promotion of a single approach to thinking about the principle. I deal with each briefly below. I should stress that identifying this tension I have no answers to it.

A study of the precautionary principle and EU risk regulation requires an engagement with diversity - diversity of contexts, legal cultures, institutions, and ideas of administrative constitutionalism. As such, the principle has an important role in helping scholars and decision-makers to think about an overlooked aspect of

European integration – administrative power. To modify fashionable terminology, the principle is concerned with the 'thru-put' legitimacy of European administrative institutions, rather than with input and output legitimacy which have tended to be the focus of European integration scholarship (Scharpf 1999). In particular there is a need to abandon quite vague concepts such as EU 'regulatory space' (Scott 2001) and the 'regulatory state'(Majone 1996) and replace them with a frame of inquiry which pays far more attention to legal and institutional detail and the way in which different paradigms of administrative constitutionalism operate (Fisher 2004). The precautionary principle's operation is likely to be controversial and its operation requires scholars, lawyers, and policy actors to take a 'hard look' at the institutional arrangements for regulating risk (Stirling, Renn and van Zwanenberg 2006).[72] This 'hard look' is particularly challenging in the EU context because there is no settled concept of the administrative sphere. While the challenges involved in needing to think about the diverse and pluralistic nature of European administrative power should not be underestimated, nor are they particularly new to scholars and decision-makers. Issues concerning the supremacy of one legal culture over another (Weiler 1999), regulatory integration (Joerges and Dehousse 2002) and legal pluralism (La Torre 1999, Snyder 1999) are constant features of European integration and the raison d'être of EU lawyers. The principle, by highlighting administrative constitutionalism in the EU, is simply adding another dimension to practical and theoretical inquiries about EU intergration (Everson 1999). This fact has not gone ignored by commentators. Ladeur in reviewing the *Pfizer* case noted, after considering the intergovernmental decision-making processes at its heart, that:

> the multi-polar character of the European administrative system might even turn out to be well adapted to the setting up of such a network-like structure

> of decision-making, thus enabling learning processes, mutual comparison, and experimentation with different types of relationships and co-ordination.[73]

Ladeur's comments suggest that the operation of the precautionary principle is an opportunity to explore more closely the nature of administrative power in the EU. I would wholeheartedly agree but be more circumspect about the opportunities for 'learning processes, mutual comparison, and experimentation'.

This is due to the developments seen above which have resulted in an approach to the precautionary principle which point in an opposite direction from those that emphasise the diversity of legal culture and administration in the EU. Over the last five years at least, there has been an increasing tendency to think about the precautionary principle in universal and formulaic terms. Not only has there been very little questioning of the logic of the European Commission's Communication but it has also been applied to all the contexts in which the principle is operating. Tentatively, I advance two possible reasons why this has occurred, both of which are closely tied to the process of European integration, albeit in different ways.

First, as Maduro argued as part of his economic constitution thesis, norms at the Community level are the most desirable basis for constitution building (Maduro 1998). As such the Commission's Communication, despite its explicit statement about its limited applicability, has become a standard for judging the exercise of all administrative power in the EU because it is an authoritative 'harmonised' understanding of the principle. This is even though those guidelines are the product of specific debates over administrative constitutionalism in areas that do not relate to how a Member State exercises power. If this is the case then inherent in integration is a tendency towards harmonising administrative constitutionalism. It is only a

tendency however, and this does raise the question of whether such harmonisation is inevitable.

Second, the reality is that due to the interconnection between different forms of state action the same rules apply even if there is no attempt to build an economic constitution. Thus for example a Member State applying to derogate under Article 95(4) must apply to the Commission to do so who will assess that decision on their own internal guidelines (Scott and Vos 2002). The close interdependence and overlap between the different contexts requiring, as a matter of practical reality, different decision-makers to take the same approach. In other words, inherent in the process of European integration may be a necessity to harmonise approaches to administrative constitutionalism. If this is the case, and I suspect it is not, then this raises some very difficult questions about the legitimacy of integration, which has tended to at least give lip service to the importance of national legal cultures.

What this tension, as well as my analysis above, highlights is that there are numerous unanswered questions concerning the operation of the precautionary principle in the EU as well as the development of risk regulation regimes more generally. Indeed, by analysing the relationship between the precautionary principle, legal culture, and administrative constitutionalism in the EU I am literally opening up a Pandora's Box of issues for scholars and decision-makers. The image of Pandora's Box is a hackneyed one but I think particularly apt for this context because the analysis above is not simply identifying future lines of inquiry but also highlighting how European integration raises some very difficult issues that once identified are not easily solved. For those that have tended to view the principle in universal terms, it is clear that this is the wrong approach as far more attention is needed to be paid to particular contexts and legal culture. At the same time however, the experimentalism

and diversity that some have argued for may not be practically possible – uniformity may be the only realistic approach in the EU to thinking about the precautionary principle and risk regulation. Moreover, to add to the complexity, what is overwhelmingly clear is that there is a close interrelationship between risk regulation and European integration - the operation of the principle highlighting the ways in which the harmonisation of regulatory regimes is not a straightforward task.[74] In particular, I would argue that the tension between diversity and uniformity in thinking about the principle and administrative constitutionalism reflects a wider tension in the process of integration.

CONCLUSION

For those wishing for the precautionary principle to be a neat and simple formula this chapter will have been a grave disappointment. Rather in this chapter I have opened up a Pandora's Box of issues concerned with the nature of administrative power in the EU by doing the following. I have shown how the precautionary principle is a flexible legal principle, the operation of which will depend on context and legal culture. I have identified the fact that the principle applies to both the internal and external exercise of state power and, in so doing, raises issues of administrative constitutionalism. I have examined the EU context and shown how the principle has six overlapping spheres of operation which highlight: the diversity of public administration and administrative constitutionalism in the EU; the fact that decision-makers are subject to competing discourses over administrative constitutionalism; and that the different spheres of operation are interdependent. I have shown how there is an increasing trend to thinking of the precautionary principle in monolithic terms. Finally, I have highlighted that there is an inherent tension between diversity and uniformity involved in the operation of the precautionary principle in the EU.

[1] I would like to thank the editors for constructive feedback on earlier versions of this paper. Any errors or omissions remain my own.

[2] I should stress that the principle also has an important role to play in other jurisdictions, in particular Australia. See (O'Riordan, et al. 2001).

[3] I say 'official' because, while this was no doubt the development of the version of the precautionary principle as we presently understand it, concepts of precaution can be seen in nearly all administrative regimes. See (Fisher forthcoming).

[4] Eg Case T-74/00 *Artegodan GmbH v Commission* [2002] ECR II-4965. Art 6 is often used as a justification for the principle applying in other sectors.

[5] A version of this definition can be found in Principle 15 of the Rio Declaration on Environment and Development; the Preamble of the Convention on Biological Diversity; and Article 10(2) of the Cartagena Protocol on Biosafety. For other formulations of the principle see (Harding and Fisher 1999) at Annex A.

[6] A distinction should be made between process and procedure. See (Jowell 2000).

[7] (Nelken 2001) at 25.

[8] In saying this I am not saying that the principle cannot be applied by either the legislature or the judiciary independently of any form of administrative action. They can be, but these cases are rare exceptions.

[9] The best example of a rational-instrumental interpretation of the precautionary principle is the European Commission's Communication on the Precautionary Principle (Commission of the European Communities 2000). For a discussion see (Fisher and Harding 2006). Rational-instrumental interpretations also arise when decision-makers are understood in adjudicatory terms. See *Conservation Council of South Australia v. Development Assessment Commission & Tuna Boat Owners Association (No 2)* [1999] SAERDC 86 and (Fisher forthcoming).

[10] This is not to say that burdens of proof, or perhaps more appropriately 'burdens of persuasion' will not have a role to play in regulatory design. See also (Jones and Bronitt 2006).

[11] The most obvious example here is the role that the principle has played in WTO Sanitary and PhytoSanitary Disputes. See Appellate Body Report, *European Communities - Measures Concerning Meat and Meat Products (Hormones)*, 16 January 1998, WT/DS26/AB.

[12] For an example of a discussion of this overlap see (McNelis 2001).

[13] This statement only stands true where there has been no harmonisation. See Case 174/82 *Sandoz BV* [1983] ECR 2445 at para. 11 and Case 54/85 *Mirepoix* [1986] ECR 1067 at para 13.

[14] Case 54/85 *Mirepoix* [1986] ECR 1067; Case 53/80 *Koninklijke Kaasfabriek Eyessen BV* [1981] ECR 409; and Case C-473/98 *Kemikalienspektionen v. Toolex Alpha AB* [2000] ECR I-5681.

[15] Case 304/84 *Muller* [1985] ECR 1511; Case 247/84 *Motte* [1985] ECR 3887; Case 178/84 *Commission v. Germany* [1987] ECR 1227; and Case 176/84 *Commission v. Greece* [1987] ECR 1193.

[16] Eg Cartagena Protocol on Biosafety

[17] Panel Report, *EC Measures Concerning Meat and Meat Products (Hormones) - Complaint by the United States*, 13 February 1998, WT/DS26/R/USA. and Appellate Body Report, *European Communities - Measures Concerning Meat and Meat Products (Hormones)*, 16 January 1998, WT/DS26/AB.

[18](Fisher forthcoming) and Appellate Body Report, *Australia -Measures Affecting Importation of Salmon*, 20 October 1998, WT/DS18/AB/R.

[19] Regulation No 2371/2002 on the conservation and sustainable exploitation of fisheries resources under the Common Fisheries Policy [2002] OJ L358/59.

[20] Eg Article 7 of Regulation No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. [2002] OJ L31/1

[21] Case 9/56 *Meroni v. ECSC High Authority* [1957-8] ECR 133

[22] Eg Case C-318/98 *Fornasar* [2000] ECR I-4785 at para. 37 and Case C-9/00 *Palin Granit OY and Vehmassalon Kansanterveystyön Kuntayhtymän Hallitus v Lounais-Suomen Ympäristökeskus* [2002] ECR I-3533 at para. 23.

[23] Case C-236/01 *Monsanto Agricoltura Italia SpA v Presidenza del Consiglio dei Ministri* [2003] ECR I-8105 at paras 110-112 and Case C-127/02 *Landelijke Vereniging tot Behoud van de Waddenzee v. Staatssecretaris van Landbouw, Natuurbeheer en Visserij* [2004] ECR I-9405.

[24] Case C-293/97 *Standley* [1999] ECR I-2603 and Case C-318/98 *Fornasar* [2000] ECR I-4785.

[25] Case C-6/99 *Association Greenpeace France v Ministere de l'Agriculture et de la Peche* [2000] ECR I-1651.

[26] Case C-3/00 *Denmark v Commission* [2003] ECR I-2643.

[27] Case C-95/01 *Criminal Proceedings Against Greenham and Abel* [2004] ECR I-1333 and Case C-41/02 *Commission v. Netherlands* Dec 2, 2004.

[28] Case 120/79 *Rewe-Zentral AG v. Bundesmonopolverwaltung für Branntwein* [1979] ECR 649

[29] Art 30 and ibid.

[30] *R (On the Application of Thomas Bates & Son Ltd) v. State and for Transport Local Government and The Regions* [2005] 2 P & CR 11 and *R(on the application of Davies) v. Carmarthenshire County Council* [2004] EWHC 2847.

[31] One could also include international organisations as well. See for example Case C-198/03P *Commission v. CEVA Santé Animale SA* 12 July 2005.

[32] Case 9/56 *Meroni v. ECSC High Authority* [1957-8] ECR 133.

[33] See the discussion in Case C-6/99 *Association Greenpeace France v. Ministere de l'Agriculture et de la Peche* [2000] ECR I-1651

[34] Article 5.1 and Annex A.4.

[35] Panel Report, *EC Measures Concerning Meat and Meat Products (Hormones) - Complaint by the United States*, 13 February 1998, WT/DS26/R/USA. and Appellate

Body Report, *European Communities - Measures Concerning Meat and Meat Products (Hormones)*, 16 January 1998, WT/DS26/AB.

[36] Consider the reasoning in Case C-6/99 *Association Greenpeace France v. Ministere de l'Agriculture et de la Peche* [2000] ECR I-1651

[37] Eg Case C-331/88 *FEDESA* [1990] ECR I-4023; Case C-180/96 *United Kingdom v. Commission* [1998] ECR I-2265; and Case C-352/98 *Bergaderm & Goupil v. Commission* [2000] I-5291.

[38] Case 53/80 *Koninklijke Kaasfabriek Eyessen BV* [1981] ECR 409; Case 54/85 *Mirepoix* [1986] ECR 1067; Case 304/84 *Muller* [1985] ECR 1511; and Case C-473/98 *Kemikalienspektionen v. Toolex Alpha AB* [2000] ECR I-5681.

[39] I say artificially because the reality is that even in this category decision-making will be influenced by EU law. See *R v. Secretary of State for Trade and Industry ex parte Duddridge* [1995] Env LR 151 and *R (on the application of Amvac Chemical UK Ltd) v. Secretary of State for Environment Food and Rural Affairs* [2001] EWHC Admin 1011.

[40] Case C-331/88 *FEDESA* [1990] ECR I-4023 and Appellate Body Report, *European Communities - Measures Concerning Meat and Meat Products (Hormones)*, 16 January 1998, WT/DS26/AB.

[41] Case C-95/01 *Criminal Proceedings Against Greenham and Abel* [2004] ECR I-1333.

[42] Case C-473/98 *Kemikalienspektionen v. Toolex Alpha AB* [2000] ECR I-5681.

[43] See the use of OIE risk assessment methodology in Appellate Body Report, *Australia -Measures Affecting Importation of Salmon*, 20 October 1998, WT/DS18/AB/R. For an analysis see (Perez 2004).

[44] As was the case in the regulatory action reviewed in Case T-70/99 *Alpharma v. Council* [2002] ECR II-3495 and Case T-13/99 *Pfizer Animal Health SA v. Council* [2002] ECR II-3305.

[45] See the regulatory action reviewed in Case C-6/99 *Association Greenpeace France v. Ministere de l'Agriculture et de la Peche* [2000] ECR I-1651.

[46] Case T-13/99 *Pfizer Animal Health SA v. Council* [2002] ECR II-3305.

[47] [1998] OJ L 351/ 4 (as amended).

[48] Article 24 of the Directive and Case T-13/99 *Pfizer Animal Health SA v. Council* [2002] ECR II-3305 at paras 29-59.

[49] Ibid.

[50] Compare Case 174/82 *Sandoz BV* [1983] ECR 2445; Case C-331/88 *FEDESA* [1990] ECR I-4023; and Case C-6/99 *Association Greenpeace France v. Ministere de l'Agriculture et de la Peche* [2000] ECR I-1651.

[51] Refer to the cases discussed above.

[52] Case C-67/97 *Anklagemyndigheden v. Ditlev Bluhme* [1998] ECR I -8033.

[53] Case 176/84 *Commission v. Greece* [1987] ECR 1193 and Case 178/84 *Commission v. Germany* [1987] ECR 1227.

[54] Appellate Body Report, *European Communities - Measures Concerning Meat and Meat Products (Hormones)*, 16 January 1998, WT/DS26/AB. There appears to be no appreciation that the WTO Dispute Panel and Appellate Body ruled differently in the *Hormones* dispute settlement process (Fisher forthcoming), (Perez 2004)

[55] This characterization is a direct product of earlier accountability crises in public administration where the division between science and politics was perceived as a way of ensuring that decision-makers did not usurp power (Fisher 2006).

[56] Case E-3/00 *EFTA Surveillance Authority v. Norway* [2001] 2 CMLR 47.

[57] Case T-13/99 *Pfizer Animal Health SA v. Council* [2002] ECR II-3305 and Case T-70/99 *Alpharma v. Council* [2002] ECR II-3495.

[58] Case T-13/99 *Pfizer Animal Health SA v. Council* [2002] ECR II-3305 at paras 162-3.

[59] Highlighted in Case C-192/01 *Commission v. Denmark* [2003] ECR I-9693 at para. 101 of the Advocate General's Opinion.

[60] At the same time the principle is used to justify in quite general terms the promotion of health protection over economic issues. See Case T-177/02 *Malagutti-Vezinhet SA v. Commission* March 10, 2004.

[61] Case C-127/02 *Landelijke Vereniging tot Behoud van de Waddenzee v. Staatssecretaris van Landbouw, Natuurbeheer en Visserij* [2004] ECR I-9405.

[62] Case C-236/01 *Monsanto Agricoltura Italia SpA v. Presidenza del Consiglio dei Ministri* [2003] ECR I-8105.

[63] Case C-192/01 *Commission v. Denmark* [2003] ECR I-9693.Case C-41/02 *Commission v. Netherlands* Dec 2, 2004; Case C-95/01 *Criminal Proceedings Against Greenham and Abel* [2004] ECR I-1333; and Case C-24/00 *Commission v. France* [2004] CMLR 25.

[64] *R (on the application of Amvac Chemical UK Ltd) v. Secretary of State for Environment Food and Rural Affairs* [2001] EWHC Admin 1011 and (Interdepartmental Liaison Group on Risk Assessment 2002).

[65] Case T-74/00 *Artegodan GmbH v. Commission* [2002] ECR II-4965; Case C-286/02 *Bellio F.lli Srl v. Prefettura di Treviso* [2004] ECR I-3465; Case C-434/02 & C210/03 *Arnold Andre GmbH & Co. KG & Swedish Match* AG Geelhoed's Opinion, 7 September 2004; and Case C-244/33 *France v. Parliament* [2005] 3 CMLR 6.

[66] See the interpretation of Case 174/82 *Sandoz BV* [1983] ECR 2445 in the Advocate General's Opinion in Case C-192/01 *Commission v. Denmark* [2003] ECR I-9693.

[67] Case C-453/03 *ABNA Ltd v. Secretary of State for Health* Opinion of AG, 7 April 2005.

[68] Case C-244/33 *France v. Parliament* [2005] 3 CMLR 6 per Advocate General.

[69] Case C-434/02 & C210/03 *Arnold Andre GmbH & Co. KG & Swedish Match* AG Geelhoed's Opinion, 7 September 2004 per Advocate General.

[70] Case E-4/04 *Pedicel AS v. Sosial- OG Helsedirektoratet (Directorate for Health and Social Affairs)* [2005] 2 CMLR 7

[71] Case C-378/00 *Commission v. Council* [2003] ECR I-937 and Case C-198/03P *Commission v. CEVA Santé Animale SA* 12 July 2005.

[72] I use the term 'hard look' on purpose to invoke the 'hard look' debates of US law in the 1970s. See *Ethyl Corp v. EPA* 541 F 2d 1 (DC Cir 1976).

[73] (Ladeur 2003) at 1479.

[74] Jasanoff has pointed to the same relationship in the context of EU biotechnology regulation. See (Jasanoff 2005).

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