The ERF Study

The Precautionary Principle
Application and Way Forward

European Risk Forum

Foreword

This study focuses on the Precautionary Principle and how it has been applied in practice and makes recommendations on better use in the future. It also provides a brief overview of the history of the Precautionary Principle, an analysis of its interpretation and use by different jurisdictions and how it has been considered by the European Courts in the judgements of various cases.

The European Risk Forum (ERF) is a specialised think tank, which for more than 10 years has been committed to making available to policymakers and opinion-formers timely, policy-orientated publications. The aim is:

- to contribute to the general debate about the best way to manage (at EU-level) risks to human health, public safety, and the environment posed by technologies, economic activity, and lifestyle choices;
- to raise awareness amongst opinion-formers and policymakers regarding risk and the use of science in regulation; and
- to promote the development, adoption, and use by the EU's institutions of modern policies, processes, and structures needed to ensure high quality risk assessment and risk management decisions at EU-level.

Alongside its publications, the ERF contributes to consultation programmes undertaken by the EU institutions and the Member States.

ERF publications usually make specific and practical policy recommendations. I hope this study provides a fruitful basis for reflection and discussion amongst all stakeholders who deal with the Precautionary Principle and the regulatory procedures related to it.

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Chairman
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Brussels, October 2011

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Introduction

This study examines how the Precautionary Principle (PP) is applied in practice, and recommends any improvements which may ensure better application of the PP by regulators in the future.

The PP is closely linked with risk assessment and risk management processes. This study will give a brief overview of the concept of risk assessment and the related limitations, challenges and benefits to such an approach, and how on the other hand risk managers have for various reasons invoked PP.

The PP was first used in environmental policy, and today it is used in a growing number of policy fields. There are various definitions of the PP, which are applied in different ways at EU and international levels.

The Commission Communication on the PP (2000) forms the cornerstone of EU policy regarding the application of the principle. This study examines the Communication and its recommendations for application of the PP, questioning whether the PP is being applied in a manner consistent with the Communication.

The public has become more vocal in recent years in demanding application of the PP, seemingly demanding the unattainable goal – zero risk. The study examines the importance of good risk communication on the part of industry and regulators to calm public fears. The role of the media, NGOs and civil society in influencing regulators in their application of the PP is not to be under-estimated. This study looks at that influence.

The PP has been applied recently in such high-profile cases as the volcano ash cloud crisis of 2010 and the BPA Directive of 2011. These two case studies will be examined in depth, with a view to helping outline underlying logics and/or differences in the interpretation and application of precaution. Furthermore, the treatment of the application of the PP by the European Courts will be addressed, focussing on the way in which the The European Court of Justice (ECJ) has developed the concept of precaution.

Leading on from the analysis above, the study will recommend ways to apply the PP today. The role of trust, perception and communication will be outlined together with the necessity for precautionary measures to be temporary. The concept of a "risk/risk" trade-off will be looked at and legislative issues hampering the proper application of the PP at EU level will be highlighted. Finally, suggestions to ensure proper interpretation and application of the Communication on the PP will be made.

Executive Summary

Chapter 1: Risk Assessment

Regulators use Risk Assessment (RA) based on science to help guide their decisions concerning industrial sectors from agriculture to chemicals, and to help them weigh the value of substances from chemicals and drugs to genetically modified organisms (GMOs). When there is too little information to understand the full implications of a substance or action, regulators may invoke the Precautionary Principle (PP) to withhold approval because of potential harm.

Use of the PP is based on technical and scientific information, and these days on psychological and sociological factors as well. The public's views can pose difficulties for administrators in instances when perceptions of risk are fed by sensationalistic reports. Some public administrators have included stakeholders in decision making in a time-consuming effort that can pay off by winning public support.

Good public communication can help the public distinguish between hazard and risk. Hazard is the potential danger itself, such as cutting yourself with a knife as you slice a tomato. Risk is the likelihood you will incur the cut. Balancing hazard against risk, many people choose to slice tomatoes for their salads.

The PP requires that risks be balanced against benefits, just as is done in the assessment of medicines or legislation. Yet for now the EU and US lack principles and methods to estimate an overall benefit-risk balance. More broadly, this lack of consistent standards means that issues can arise because of local cultural or sociological conditions. That may help explain why one set of issues gains notice in the US, while an entirely different set of issues raises concerns in Europe.

The absence of public involvement is no guarantee that decisions will be made on a strictly scientific basis. Japan has seen its traditional cosy consensus-and-negotiation system challenged by an overly close relationship between government and industry, exacerbated by problems at the 2011 Fukushima nuclear accident.

Chapter 2: The Precautionary Principle

The Precautionary Principle (PP) is applied when there is a need to err on the side of caution because of uncertainties about the safety of technologies or infrastructure.

The European Commission says use of the PP pre-supposes discovery of potentially adverse effects from a phenomenon, product or process, but with scientific data so fragmentary, inconclusive or imprecise that risk cannot be determined. The 1992 Rio Declaration said that when *"there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation"*. WTO agreements also recognise the PP, but the OECD has no guidelines on it. The US declined to sign up to the PP and Japan uses the softer term "precautionary approach", and has exceptions to that. Developing countries have expressed concern the PP can be used as a non-tariff trade barrier.

The PP comes in more than one form. Strong precaution requires regulation to combat potential health, safety or environmental risks, no matter that evidence is weak and the economic costs are high. Weak precaution permits use of the PP but stops short of requiring preventive action in the face of uncertainty.

The European Commission published a Communication in early 2000 aimed at stirring debate rather than being the final word on the PP. It describes the PP as part of risk analysis rather than something that stands alone. However, it provides no concrete definition of the PP.

Instead, the Communication seeks to build a common understanding of how to assess, appraise, manage and communicate risks that science cannot fully evaluate. It tries to guard against the use of the PP as a disguised form of trade protectionism, especially given its political nature. The PP cannot be an excuse to seek zero risk, which almost never exists. The Council and the European Parliament responded to the Communication with resolutions on the issue.

The use of the PP requires a full scientific evaluation of risk and the potential consequences of inaction. The review should be open and permit all interested parties a chance to study the available options.

The Communication says that decision makers should also consider the proportional risk (not zero risk), and apply the PP in a non-discriminatory manner, as well as being consistent with past practice. They should also take into account the potential costs and benefits of action, or a lack of it, relying on scientific data. Finally, they should assign the burden of proof to one party or set of interests, which has the responsibility for a more comprehensive risk assessment.

The European Court of Justice (ECJ) and the lower General Court had referred to the PP in 140 cases by 2008, finding that the element of proportionality is important end emphasising that risks must be real, not hypothetical. However, unlike the Commission's Communication, the Court's case law has not emphasised the temporary character of the PP.

A fundamental problem is that the PP lacks a universal definition, leading to inconsistent application.

Chapter 3: Communication and Expectations

The public perception of risk has inevitably been a factor in application of the PP. Some believe this is a mistake, and that sound science alone should be the basis for decisions. But others say that decision makers will be sloppy and fail to apply high scientific safety standards without public pressure.

The ECJ has ruled the European Commission can reject scientific advice from its advisory committees without explaining the scientific reasons for doing so. That leaves the door open for the Commission to take into account public perception.

Public perception can be tricky. Researchers say that even if a risk is very low, individuals will not accept it if they perceive no balancing benefit. When the benefit is zero, the risk-benefit ratio is always too high. Communicating the risks and benefits can be difficult given the complexity of issues and the sometimes mixed evidence available. Some researchers suggest that policymakers study public fears and use that understanding to formulate their messages.

Industry's concern is that an overly cautious interpretation of the PP may stifle innovation and hinder new products from reaching market. Industry generally calls for any use of the PP to be temporary in nature and to take into consideration costs of any precautionary measures.

By contrast, civil society and NGOs tend to favour a strict version of the PP, reflecting concerns about protecting the end user. NGOs and civil society promote their strict version of the PP because it is seen as a more suitable process than risk assessment.

The media plays a major role in influencing public perception of risk, but so do professional networks, informal networks of friends and social media.

History has shown potential public health risks are likely to become major stories when there are questions of blame or alleged secrets and attempts to cover up. Media focuses

on individuals, so human interest through identifiable heroes, villains and victims really matters, as do links with high-profile people or issues. Conflict and a story as a portent of future ills is important, as is the possibility of a large number of people exposed to risk, even low-level risk. Finally, links to sex or crime build interest in a story.

Given that the European courts are evolving to take into account public views no matter what scientific evidence may say, political communication has taken a stage-front role in the application of the PP.

Chapter 4: Case Studies

Many of these points are illustrated by Case Studies in Chapter 4, including the Volcano ash cloud crisis of 2010, the European BPA directive of 2011, precaution in the application of EU case law, the Pfizer case, the Paraquat case, the Artegodan case, the Pfizer / Alpharma cases, the Sandoz case and the Gowan case.

Chapter 5: Conclusions and Recommendations

The PP has sometimes been invoked because of public concerns, often arising out of a lack of trust. That has made political communication of key importance in application of the PP.

Effective communication that distinguishes between hazards, risks and uncertainties can help to restore public confidence in the competence, independence and fairness of those making decisions. This will strengthen the legitimacy of government action and improve compliance and enforcement.

This study recommends the European Commission seek to integrate its PP communications with other guidelines such as those on impact assessment into a coherent set of guidelines. In addition, the comitology framework should make risk impact assessments mandatory when the PP is invoked. Consideration should be given to an Administrative Procedure Act that would consolidate guidelines.

Regulators and courts should rely on the best scientific evidence even in the face of critical public opinion, aiming to mitigate risk rather than eliminate or mitigate hazards. Cost-benefit analysis and risk-risk trade-offs are vital. No absolute absence of risk can be proven and therefore it should not be required.

The application of the PP should be provisional and proportionate by definition. Any application of the PP should specify the risk being addressed and define what knowledge is missing; restrictions should be revisited after a set period and adjustments made based

on the knowledge gained in the interim. Precautionary decisions should have a sunset provision after which the rule ends.

The PP should be subject to an impact assessment that balances known risks, takes into consideration trading partners, and balances the risk of regulatory intervention with risks to safety.

Industry must recognise the necessity of continuous dialogue with consumers, regulators and other stakeholders. In doing so, EU institutions should set a formal and binding policy for communications.

Chapter 1: Risk Assessment

Risk Assessment – Definition & Limitations

In a world of many unknowns, the risks of our actions need to be constantly assessed and managed. Decision-makers must take risks into account to reach the best possible decisions. Risk assessment (RA) is a tool for decision making.

For many regulators, RA, just like the Precautionary Principle (PP) is part of the wider risk management in the process of identifying, assessing and prioritising risks and implementing plans to address these. Risk control will aim to either limit the negative consequences or to maximise the realisation of opportunities.

RA is the process that determines the value of risk related to a concrete situation and a recognised threat or hazard, which can be linked to life, health, property or environment.

Regulatory requirements to assess risk exist in a range of industrial sectors such as agriculture, pharmaceuticals, chemicals and food, and cover such products as new drugs, pesticides, genetically modified organisms (GMO), and chemicals. The RAs required by the regulations are science-based and precautionary in nature.

There are many methods to conduct RA. The traditional approach has three steps:

1. *Hazard Identification*: a determination of potential adverse consequences of the product or action, and the strength of the evidence;
2. *Exposure-Response Analysis*: a determination of the relationship between the exposure to the hazard and the probability of resultant harm; and
3. *Exposure Assessment*: a determination of the exposure of individuals, populations or the environment to the hazard and hence the degree of harm that they might suffer.

The results of these three steps are then combined to estimate risk.

RA is the determination of the probabilistic relationship between the exposure to a certain hazard (such as a knife) and a resultant harm (such as a cut). In its simplest form, the subsequent risk management action consists of determining the degree of harm considered acceptable, and then setting an exposure limit.

However, limits to RA arise quickly. For many risks the scientific base is too uncertain to carry out a full RA. Until science delivers its findings, the PP applies for the protection of

public health and the environment in the EU[1]. The PP and its role in the EU are discussed in the following section.

The RA procedure depends on what is known and is thus by its nature retrospective. However, where there is limited evidence that a significant risk might exist, risk management must then be prospective. It has to consider the acquisition of new information through precautionary research and to the introduction of proportionate, precautionary risk management actions.

Figure 1 is taken from a 2003 European Commission Technical Guidance Document on RA in the context of biocidal products.[2] It shows the various stages of the RA process.

1 For a more complete analysis see, for example, Rogers, M. D., 2003. Risk Analysis under Uncertainty, the Precautionary Principle, and the New EU Chemicals Strategy. Regulatory Toxicology and Pharmacology, 37, pp. 370-381.

2 European Commission (2003) Technical Guidance Document on Risk Assessment in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances & Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market

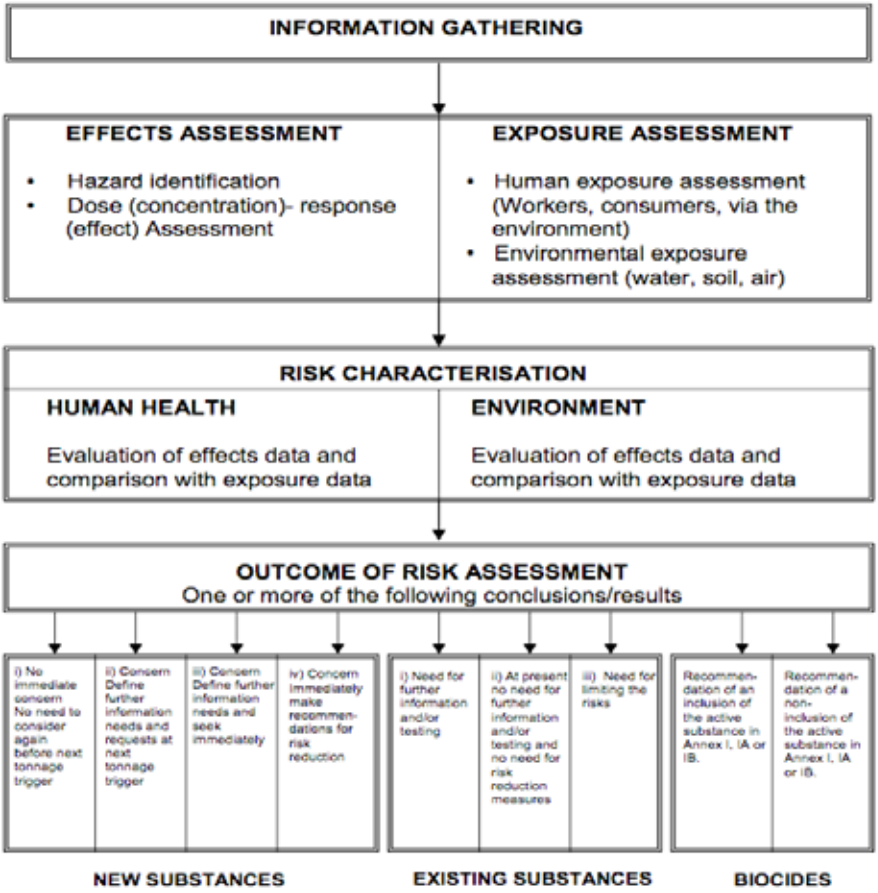

Figure 1 Risk assessment of new substances, existing substances and biocidal active substances and substances of concern present in a biocidal product: general principles.

Challenges

Several global trends such as scientific and technological advances, population growth and globalisation increasingly expose us to new risks, which are difficult to fully understand, influence and control. These trends also challenge the way we perceive risks and deal with them. In dealing with these complexities and the limited amount of data, the question arises of how to incorporate these challenges into existing legislation. Furthermore, existing legislative procedures do not allow for fast adaptation to the acquisition of new knowledge and the emergence of new risks. Approaches to risk vary across jurisdictions and the globalisation of risks will require increased cooperation in risk governance.

The assessment of risk was once limited to a technical and scientific approach, but has evolved to include psychological and sociological factors that contribute to public perceptions of risk. Individuals have demanded more say as their trust in experts and decision-makers has declined. This change has been fed by the focus of modern media on risks, and sometimes a public, whose concerns are stoked by alarmist news stories, clashes with experts who appeal to scientific evidence.

Public administration has evolved and adopted the approach of "risk governance", in which stakeholders are involved in the development and implementation of risk management policies. The advantage of this approach is a wider input of knowledge, experience and views, which lead to policies that are more likely to have general support. The disadvantages are that it may make the process more laborious and challenging as issues become more complex, uncertain and ambiguous.

What About Benefits?

Currently the emphasis of RA is, as the term suggests, on risks. The optimal degree of intervention, however, results from a balance between risks and benefits of a product or an action. Benefit is measured by evaluating available alternatives, one of which being to refrain from the risk-producing activity.

A benefit-risk assessment whereby benefit and risk are evaluated is a common approach in the scientific evaluation for drugs in the EU. EU law requires that a committee of the European Medicines Agency find a positive benefit-risk balance (Article 26 of Directive 2001/8) for new medicinal products.

The European Commission usually uses a cost-benefit analysis to assess the potential economic, social and environmental consequences of proposed new laws (Regulatory Impact Assessment). By contrast, RA is only one step in the process and therefore ignores possible benefits and weighs only risk.

The EU and US still lack guidance on principles and methodology for estimating an overall benefit-risk balance. Such principles would include benefit and risk criteria and a description of the way the evidence is weighed for a risk-benefit assessment.

The question is: how can we move to a more balanced and holistic approach to RA that includes the analysis of benefits?

The Global Debate / A Global Comparison

It is often argued that US and EU risk regulations have moved in opposite directions. Generalising statements indicate the US as less risk-averse and the EU as more precautionary because of the different cultural roots or the features of the two political and institutional contexts. Another rather superficial perspective suggests that the dichotomy across the Atlantic is chronological – until the mid-1980s health, safety and environmental risk regulation was generally stricter in the US than in the EU, but since the mid-1980s the EU has become increasingly active in establishing consumer and environmental regulations that are now more restrictive than in the US.

Vogel (2001:1) points out that the shift to increasingly risk-averse and stringent regulatory politics and policies in the EU is primarily due to the increased competence of the EU, broader public concern for health, safety and environmental protection, and a series of regulatory failures that have undermined public trust in government regulation in Europe. He states that politics and policies have become *"politicised, highly contentious and characterised by a suspicion of science and a mistrust of both government and industry"*.

As a consequence, the PP has emerged as an influential approach to both consumer and environmental protection (Vogel, 2001). It has often allowed the adoption of rather risk-averse policies in Europe.

Recent, comprehensive research (Wiener et al., 2011) solidly points out, however, that Europe and the US have maintained rough parity across a wide range of regulated risks over the past 40 years. Screened case studies in food safety, air pollution, climate change, nuclear power, tobacco, chemicals, marine biodiversity and terrorism suggest that pronounced differences between the two sides of the Atlantic are located in highly particular controversies over specific cases. While Europe has been more precautionary about some risks, the US has been more precautionary about others, both recently and in the past. Moreover, Wiener et al. argue that there has been significant variation within each jurisdiction, both across risks and Member States and agencies. The authors conclude that hybridisation" is a more accurate description of precautionary trends between the EU and the US. Substantial exchange, diffusion and borrowing of ideas have shaped the reality of precaution.

Government regulation depends increasingly on scientific evidence, and regulatory policy-making is becoming more open to public participation and more responsive to public concerns. This means a greater role for public opinion and NGOs in shaping risk management decisions.

In January 2011, US President Obama signed a new executive order[3] that lays out a set of principles for future rulemaking. It requires federal agencies to design cost-effective, evidence-based regulations that are compatible with economic growth, job creation, and competitiveness.

Regulations must be guided by objective scientific evidence, must take into account benefits and costs, both quantitative and qualitative, ex-post review should be carried out systematically, and existing regulations must be reviewed and replaced if they are outdated. The principles of "equity", "human dignity" and "fairness" show a shift towards more "qualitative" analysis. It will be interesting to see what balance will be found between the economic and the risk rationale.

In Japan, since the 1990s administrative acceptance of risk assessment and management practices has caught up with international trends. There are differences, however, in approaches to RA, which reflect different social and cultural backgrounds. For example, in Japan negotiation and consensus building are very important to decision making on the regulation of environmental pollution, whereas in the US more emphasis is placed on rigorous scientific analysis and open discussion. The 2011 nuclear crisis in Japan, and the failure of the Japanese Government to acknowledge radioactive risk until after an embarrassing public announcement by US monitors, has pointed a finger at the failure of regulation and the overly close relationship between regulators and the regulated in Japan.

Rapid industrialisation from the mid-1950s to the mid-1960s was accompanied by intense environmental problems that resulted in serious health injuries to the population. In 1967, the Basic Law for Environmental Pollution Control was passed to set an environmental quality standard, or goal, for pollutant reduction. Subsequently, specific standards were set for ambient air, water, and soil pollution and for noise.

In 1993, Japan replaced the 1967 Basic Law for Environmental Pollution Control with the Basic Environment Law, which defines the basis of policies for environmental conservation consistent with sustainable development. The Basic Environmental Plan, which was established as a long-term comprehensive national plan for environmental conservation under the Basic Environment Law, requires the development of risk assessment and management practices as measures against hazardous chemical substances in the

3 http://www.whitehouse.gov/the-press-office/2011/01/18/improving-regulation-and-regulatory-review-executive-order

environment.

Risk Assessment in the EU

In the EU, principles of RA are laid down in numerous pieces of legislation and Commission documents. Such documents also refer to principles of risk management, a topic that is not within the remit of this study, although it is clear that invoking PP is part of risk management. Furthermore, the EU Treaty has references to scientific evidence and data as a basis and justification for policy and measures. EU documents which define RA and risk management, as well as related rules and principles include the following:

- Commission Communication on Consumer Health and Food Safety (1997)
- Commission Communication on Collection and Use of Expertise (2002)
- EU Regulation 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)
- Commission Decision establishing Scientific Committees in the field of Consumer Safety, Public Health and the Environment (2004, revised 2008)
- Old chemicals legislation such as the Dangerous Substances Directive[4] the REACH Regulation[5]; the Plant Protection Products legislation[6] and EU Pharmaceuticals legislation.[7]

To a great extent, similar principles and requirements are applied in relation to all EU agencies. Although there are no overarching set of rules and principles for risk assessment and management at EU level, several documents and instruments include horizontal RA principles. Rules of procedures, working practices and methodological guidelines reflect the same principles, with practical adaptations to specific needs.

The EU's RA system uses a number of independent bodies, which give scientific advice to decision makers. The underlying principle is that EU policy is to be based on best available and independent scientific knowledge. These bodies operate within their specific legal

4 Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labeling of dangerous substances.

5 Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

6 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market.

7 The body of European Union legislation in the pharmaceutical sector is compiled in Volume 1 and Volume 5 of the publication "The rules governing medicinal products in the European Union".

frameworks but cooperate closely to ensure consistency in their methodologies and for sharing experience and best practices on RA.

The EU RA system includes a number of committees and agencies, such as the three Scientific Committees managed by the European Commission's Directorate-General for Health and Consumers – the Scientific Committee on Consumer Safety (SCCS), the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIR) – the European Food Safety Authority (EFSA), the European Medicines Agency (EMA), The European Chemicals Agency (ECHA), the European Centre for Disease Control and Prevention (ECDC), the European Environment Agency (EEA), the European Aviation Safety Agency (EASA), the European Network and Information Security Agency (ENISA), and the Scientific Committee on Occupational Exposure Limits (SCOEL).

The European Commission regularly organises information sessions and conferences to promote dialogue among these committees, the European Parliament and stakeholders.

The Europe 2020 strategy launched by the European Commission in March 2010 aims to deliver "smart, sustainable and inclusive growth". Environmental considerations are at the forefront of the Strategy – building a competitive low-carbon economy that makes efficient, sustainable use of resources, protecting the environment, and preventing biodiversity loss.

The aim to have smarter regulation will include evaluating and further improving guidelines of regulatory processes. If this is done correctly, the temporary nature of the PP should be adhered to and should increasingly be followed by further evaluation.

Chapter 2: The Precautionary Principle

Definition

As mentioned in the preceding chapter, the Precautionary Principle (PP) is an acknowledgment of the limits of the RA process. For many risks, the scientific base is too uncertain for a full RA and it is in these instances that the PP applies.

But what is the PP? Although there is no universally accepted definition, it is clear that it is an approach that may be used by policymakers in the risk management process where urgent measures are needed in the face of a danger to human, animal or plant health, or to protect the environment where scientific data do not permit a complete evaluation of the risk. Most definitions of the PP contain the following four elements:

1. Element of threat;
2. Element of uncertainty;
3. Element of action;
4. Element of command.

It is the elements of action and command that differentiate "strong" and "weak" versions of the PP. Different versions of the PP vary as to the extent to which they imply action must be taken where uncertainty exists, and in terms of the type of the action required. Strong precaution requires regulation whenever there is a possible risk to health, safety, or the environment, even if the supporting evidence is speculative, and even if the economic costs of regulation are high. Weak precaution is not as restrictive and allows preventive measures to be taken in the face of uncertainty, but does not require them.

Origins & Approaches

The PP emerged largely as a result of an increased awareness of the need for sustainable development. In this context, it is an indication of the need to err on the side of caution when uncertainty arises in the implementation of technological and infrastructural development. The PP is generally meant to lay the burden of proof on those who may be creating potential risks to the public interest in the broad sense, which is also to say that the intent is to err on the "sustainability" side of the sustainable development equation.[8]

8 For more see Hepburn, J., Cordonier Segger, M.C. & Gehring, M., 2005. The Principle of the Precautionary Approach to Human Health, Natural Resources and Ecosystems. CISDL "Recent Developments in International Law Related to Sustainable Development", Series 1, March 2005.

At an international level, the PP was first recognised in the World Charter for Nature in 1982. It was subsequently incorporated into various conventions on the protection of the environment including the 1992 Rio Declaration, which states that *"in order to protect the environment, the precautionary approach shall be widely applied by States according to their capability. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation"*.

The PP first appeared in the EU legal framework in the EC Treaty (Maastricht, 1992), which refers to the principle in the title on environmental protection. This reference to the PP is carried over into the Lisbon Treaty (new Article 191), still in the context of environmental protection, with a new reference to combating climate change. Although the PP is only referenced in the treaties in the context of the environment, in practice, the scope of this principle is far wider and also covers consumer policy and human, animal and plant health.

The PP is also mentioned in some non-binding Community documents, for example, the Commission's Impact Assessment Guidelines (15 January 2009) (pp 25, 38 and Annex 12) and it forms the basis of a Commission Communication in 2000, which is discussed in detail below.

Over the years, the PP has been included in a number of WTO agreements, supporting the proposition that it has become a general principle of international law. The US, however, does not subscribe to this view, stating in 2004 *"the United States submits – precaution is not a principle of international law […] precaution cannot even be defined"*.[9] This highlights the opposition towards the principle in the US, where there is a view that use of the PP constitutes risk avoidance and is damaging to the economy. Indeed, the US Chamber of Commerce states that it opposes the domestic and international adoption of the PP as a basis for regulatory decision-making.

Japan has also had concerns regarding the application of the PP and is seen to prefer the term "precautionary approach" instead of the term "precautionary principle". This is probably because the term "principle" has special connotations in legal language, because a "principle of law" is a source of law. Thus, the term "approach" is generally considered to be a softening of the term "principle". There are a number of controversial policy areas where Japan has refused to apply the PP, for example with regard to whaling activities and the fishing of bluefin tuna. However, Japan advocated a strong version of the PP in the wake of the bovine spongiform encephalopathy (BSE) crisis in 2003, by suspending importation of all beef from the US.

9 29 July 2004 – Executive Summary Submission of the Rebuttal Submission of the United States – WTO vs. European Communities.

In contrast, the EU has embraced the PP and it has been widely applied by its institutions in their policymaking. It will be interesting to see whether this trend will continue and whether an increase in the use of PP will be apparent over the coming years. It is significant that one of the main themes of the Europe 2020 Strategy is sustainable development, which, as already mentioned, is an area that favours a precautionary approach.

At present, there are no OECD guidelines on the PP, adding to the divergence in application of the principle between the EU and the US.

A further topic for thought is how developing countries will implement the PP. Many are uncertain about what to do. They need economic growth, but do not want to sacrifice their futures by accepting risks that have high long-term costs. They also want to maintain access to markets, but are concerned about the cost of complying with precautionary principles and the potential for them to be used as non-tariff trade barriers, which limit access to markets.

Commission Communication

Background

In February 2000, the European Commission published a Communication on the PP[10] providing a general framework for its use in EU policy. The Directorates-General for the Environment, Enterprise, and Health & Consumers all contributed to the drafting of the Communication. It was a response to the Council Resolution of 13 April 1999[11] requesting the Commission develop clear and effective guidelines for the application of the principle.

The Communication describes the use of the principle in a range of policy areas and says that the PP must be viewed in the overall framework of risk analysis. What the Communication does not do, however, is provide a concrete definition of the PP.

Instead, the Communication seeks to build a common understanding of how to assess, appraise, manage and communicate risk where science is not yet fully able to evaluate it. It lays down the checks necessary to avoid inappropriate use of the PP and to prevent it being used as a disguised form of trade protectionism. To this end, it stresses that the PP may only be invoked in the event of a potential risk and that it can never justify arbitrary decisions.

10 Commission Communication of 2 February 2000 on the Precautionary Principle, COM(2000) 1.

11 Council Resolution of 13th April 1999 on the Precautionary Principle, OJ C 206, 21.7.99, p.1

The Communication makes it clear that there is an important distinction between the decision to act or not to act and notes that this decision is of a political nature. Furthermore, the PP is a not a substitute or excuse for seeking zero risk. The Commission has stated that zero risk is rarely found, and that in the vast majority of cases we are in the field of managing and controlling risk.[12]

The Communication was billed as a document which tries to "stir the debate" rather than being the final word on the PP and, indeed, it subsequently provided a basis of discussion in the Council and the European Parliament, with both institutions passing resolutions on the issue.[13]

Use of the PP

As the Communication stipulates, the PP pre-supposes identification of potentially adverse effects resulting from a phenomenon, product or process and a scientific evaluation of the risk which, because of the insufficiency of the data, or their inconclusive or imprecise nature, makes it impossible to determine with sufficient certainty the level of the risk in question.

When invoking the PP, it must be borne in mind that in some cases the right answer may be to do nothing, or at least not to introduce any legally binding measure. If action is deemed the right course there are a wide range of initiatives available, from legally binding measures to recommendations for extra controls, to the launch of a research project.

The PP should be informed by three specific principles:

1. Implementation should be based on the fullest possible scientific evaluation.
2. Any decision to act or not to act must be preceded by a risk evaluation and an evaluation of the potential consequences of inaction.
3. All interested parties must be given the opportunity to study the various options available, whilst ensuring the greatest possible transparency.

In addition to these specific principles, the general principles of good risk management will also be applicable where the PP is invoked. These are contained in paragraph 6.3 of the

12 Address by David Byrne on the Precautionary Principle – The Economist Conferences, Paris, 9 November 2000.

13 European Parliament Resolution on the Commission Communication on the Precautionary Principle (COM(2000) 1 – C5-0143/2000 – 2000/2086(COS)) and Council Resolution on the Precautionary Principle, Annex III to the Presidency Conclusions of the Nice European Council Meeting, 7-9 December 2000, SN 400/00 ADD 1 (2000).

Communication, which states that measures must:

1. be **proportional** to the chosen level of protection and must not aim at zero risk;
2. be **non-discriminatory** in their application (i.e. that comparable situations should not be treated differently and that different situations should not be treated in the same way);
3. be **consistent** with similar measures already taken;
4. be based on an **examination of the potential benefits and costs** of action or lack of action (i.e. the measures envisaged must produce the overall advantage of reducing risks to an acceptable level; the examination should include an economic cost/benefit analysis when this is appropriate and feasible; other analytic methods, such as those concerning efficacy and the socio-economic impact of the various options, may also be relevant);
5. be **subject to review, in light of scientific data** (i.e. the measures, although provisional, shall be maintained as long as the scientific data remain incomplete, imprecise or inconclusive, and as long as the risk is considered too high to be imposed on society; meanwhile, scientific research should be continued with a view to obtaining more complete data); and
6. indicate responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment (i.e. assign the **burden of proof**).

As this Communication is not legally binding, it is interesting to note how and to what extent it has been applied by the institutions. In this regard, a glance at the case law of the European Court of Justice proves instructive.

EU Case Law

As the Communication on the PP states, like other general notions contained in the legislation, such as subsidiarity or proportionality, it is left to the decision-makers and the courts to flesh out the principle.

In the European Court of Justice (ECJ), early judicial shaping of the PP began in the BSE cases of the mid-1990s, where the EU enforced a temporary ban on British beef on public health grounds. It was held that *"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"*.[14]

14 Case C-157/96, National Farmer's Union Case, para. 63; Case C-180/96, UK v Commission, para. 99

By 2008, some 140 cases in the ECJ and the General Court (GC, formerly the Court of First Instance) had referred to the precautionary principle, including 88 judgements and orders and 52 opinions.[15]

The case law shows that the element of proportionality is important in implementing the PP. The courts have emphasised that risks must be "real" and not "hypothetical". However, no judgements have noted that uncertainty in the scientific evidence could be reduced by research, that is to say, the temporary character of the PP as highlighted in the Commission Communication has so far not been reflected in the case law.

It is possible that court may not be the best arena for settling stakeholder interests and that a new Communication on the PP might encourage alternative approaches to the management of uncertain risks.

A more detailed analysis of the case law on the use of the precautionary principle can be found in chapter 3, below.

Challenges

Advocates of both the strong and weak formulations of the PP have criticised the principle for being too weak and too strong, respectively.

A rigid application of the PP may ignore risks associated with avoiding the proposed activity or policy, perhaps allowing concern for potential negative impacts to force a ban on a technology that offers distinct advantages. Under such a scenario, the mobile phone might not have been permitted until it could be proved not to cause cancerous tumours.

Associated with this is the claim that use of the PP is impractical, since every implementation of a technology carries some risk of negative consequences.[16] In this sense, the PP can discourage research and development by causing uncertainty and rendering it costly and impractical thus hampering valuable innovation.

Cameron (2006) notes the danger of using the precautionary principle as a protectionist barrier saying it can be *"open to misuse and opportunistic manipulation by rent-seeking and commercial interests."*[17] Thus, a competing product could be opposed on the grounds of potential harm. According to Cameron, it already has been *"implicated in number of trade*

15 Figures from Health Council of the Netherlands, 2008, Prudent Precaution, publication no. 2008/18E

16 See Sunstein C.R., 2002. The Paralyzing Principle – Does the precautionary principle point us in any helpful direction? The Cato Institute, Winter 2002-2003.

17 At page 15

disputes. An example is the European Union imposing import barriers on hormone treated beef and genetically modified food products."[18]

As mentioned earlier, the European courts have never highlighted the temporary nature of precautionary measures. The Commission Communication declares that precautionary measures must be reviewed in light of scientific data, but offers no guidance on when or how, which has led to the PP being treated as an end point instead of a way station.

Overall, the fundamental problem is that the PP lacks a universal definition. This has led to claims that because there are so many definitions and formulations floating around, the principle is ambiguous and cannot be dealt with consistently. Despite this ambiguity, it is a principle that remains popular with the public, which generally believe it is "better to be safe than sorry". This highlights another major challenge – that the concept of the PP and its uses may not be properly understood by the public. For example, as Sunstein (2008) points out, the public assume that nature is benevolent and harmonious and that natural chemicals are safer than man-made chemicals, but most toxicologists would disagree. Studies show that people overestimate the carcinogenic risk from pesticides and underestimate the risks of natural carcinogens. There is a clear problem of communication here, with policymakers and the public at odds as to what level and type of risk is acceptable. In part, the view of the PP has been shaped by NGOs and civil society, and we now turn to their role.

18 At page 15

Chapter 3: Communication and Expectations of the Precautionary Principle

1. Communication by Regulatory Bodies

Public Risk Perception

Whether public risk perception should be a stimulus for invoking precautionary measures in risk management is a sensitive question.

Opponents to the use of public risk perception in this way stress the point that risk management should be based on sound science using the best available scientific evidence. They assume that perceived risk differs from assessed risk, in that it may more readily be manipulated.

Proponents argue that public risk perception should be taken into account in decisions about risk management: when the public is concerned about a risk, risk managers should address these concerns by invoking additional protective measures. Furthermore, they underline that societal values and public willingness to accept a risk are key factors in determining a society's level of protection.[19]

On this point, it is worth noting that the ECJ in the recent Gowan case refrained from imposing on the EU institutions, when they are departing from the scientific opinion of their committees, a duty to provide a *"statement of reasons […] of a scientific level at least commensurate with that of the opinion in question"*.[20] Examining this judgement, Alemanno (2011) suggests that the Court is implicitly indicating that the Commission may adopt the PP in response to public concerns, regardless of its scientific foundation and without actually stating the reasons behind the action. In other words, by relying exclusively on perception and public concern, inappropriate and disproportionate long-term measures may be taken in spite of the existence of RA and instead of an appropriate public communication.

19 See Wiedemann P.M., Schütz H. (2005) The Precautionary Principle and Risk Perception: Experimental Studies in the EMF Area. Environ Health Perspect 113:402-405. doi:10.1289/ehp.7538

20 Pfizer, at 199

Risk Communication

The term "risk communication" arose largely as a result of environmental controversies in the 1970s, when public concern was high about some relatively low threats to human and environmental health. Scientists, regulators and industry perceived the general public as irrational, and their frustration gave rise to efforts to educate the public and defuse those controversies. In these early days, risk communication was thought of as a one-way process in which experts would explain the facts to the ill-informed lay public in ways that would help people behave more rationally. Indeed, early risk communication has been described as a *"codeword for brainwashing by experts or industry"* (Jasanoff, 1989).

Now however, there is a growing acceptance that risk means something inherently different to the lay public than it does to scientists and regulators. Risk communicators are learning to understand and respect lay perceptions of risk, which is an important step in effective risk communication.

It is important to understand the individual risk-benefit analysis that members of the public carry out. This individual risk-benefit analysis usually drives one to reject an individual risk if it is not counterbalanced by an individual benefit. Interestingly, a collective benefit, such as access to technology, does not compensate for an individual risk. Even if the risk is very low, if individuals perceive absolutely no balancing benefit, they will not accept the risk: when the benefit is zero, the risk-benefit ratio is always too high.[21]

A major problem in communicating the risk of an activity and whether the PP should be applied is the complexity of some of the policy issues concerned and the scientific controversies that surround them (e.g. GMO, electromagnetic fields, aspartame, etc.). The results of scientific studies sometimes appear contradictory, and, coupled with the lack of conclusiveness of many studies, can trigger endless scientific debates. This is exacerbated when the risk relates to severe disease, such as cancer, or to specific groups, such as children.

A good illustration of this point is the recent banning of Bisphenol A (BPA) in baby bottles, as highlighted in the Case Study below. Despite the fact that the European Food Safety Authority (EFSA) found no risk to health, a ban was enforced due to public concerns surrounding the issue. The fact that there was a hazard but not a risk (and the difference between these terms) was not effectively communicated to the public. Furthermore, industry failed to communicate the possible benefits of the use of BPA over other substances. This may indicate that regulators find it easier to ban a product rather than communicate to consumers why a ban should not be put in place.

21 Executive Agency for Health and Consumers, "Promoting healthy environments: Electromagnetic fields", August 2010, p.33.

Gray & Ropeik (2002) say that policymakers must strive to help people keep their perception of risk in some kind of reasonable perspective. Policymakers must study the fears of the public, and use that understanding in formulating their messages. Gray & Ropeik have outlined consistent characteristics of risk that form the basis of the public's perceptions:

- **Awareness**: As our awareness of a risk arises, so does our fear.
- **Uncertainty**: The more uncertain we are, the more afraid we are.
- **Is the risk personal?** We are more afraid of risk if it puts us in personal peril than if it threatens somebody else.
- **Optimism bias**: Even when people have a greater fear of risk, they consistently believe that the risk is more likely to happen to someone else.
- **Is the risk new?** We are generally more afraid of new risks than risks we have lived with for a while.
- **Is the risk catastrophic?** We are more afraid if a risk will kill a lot of people all at once in one place than we are of risks that may kill the same number of people but are dispersed across time and location, such as heart disease.
- **Is the risk voluntary?** We are more negative about risks that are forced on us than those that we choose.
- **Control**: We are less afraid of a risk if we have some control over events.
- **Trust**: The more we trust the people who are supposed to protect or inform us of the risk, the less afraid we will be.

These factors should be kept in mind by policymakers and industry when communicating risk to the public. Gray & Ropeik also argue that risk communication must become an integral part of policymaking and that it should be seen as more than just a way of responding to a particular crisis at hand; rather, it is vital in helping prepare for the next crisis.

Regulators must remember that in most circumstances, messages are judged first and foremost not by content but by source: *who is telling me this, and can I trust them?* If the answer to the second question is "no", *any* message is liable to be disregarded, no matter how well-intentioned and well-delivered. Therefore, trust is crucial. Such trust is generally fostered by openness, both in the sense of avoiding secrecy and in the willingness of regulators to listen. It is vital not to trivialise risk and patronise an audience, because once trust is lost, re-establishing it is a long uphill task.

That is why dialogue between all stakeholders is necessary in relation to decisions on the application of the PP. Ropeik (2008) believes it essential to be transparent, open, honest,

accountable, and to respect the validity of the lay public's intuitive reasoning about risk. Two-way risk communication that takes into account the feelings and values of the audience, is likely to be more effective than one-way communication that offers only facts.

However, as a counter-argument to this view, it has been shown that the more the public knows about a risk, the more fearful they become. Wiedemann conducted two comparably designed experiments to evaluate whether precautionary policies affect the lay person's perception of the level of risk associated with mobile phones (Wiedemann & Schütz, 2005; Wiedemann et al, 2006). The first experiment was conducted in Austria and the second in Switzerland using German and French speaking subjects. In both experiments, the subjects who received information about precautionary measures expressed a higher perception of risk than subjects who did not receive the information.

These counter-intuitive findings are of particular importance to regulators and policymakers, since they show that disseminating information about precautionary measures does not necessarily decrease risk perception. Clearly, the challenge is to communicate the reasons behind taking precaution so that additional measures are seen as indicators of increased safety, rather than as a confirmation of the existence and seriousness of a risk.

2. Industry Perception

The prevailing view is that industry favours a rational, science-based application of the PP as set out in the Commission Communication. It is in the interest of industry that its products do not harm consumers, the environment or workers, and so it applies its own precautionary approach. Industry's concern is that an overly cautious interpretation of the PP may stifle innovation and hinder new products reaching the market. Industry generally calls for any use of the PP to be temporary in nature and to take into consideration the costs of the precautionary measures.

Some sectors in industry have been reluctant to engage in risk communication with the public, believing that the science behind an issue will be too complicated for the public to understand. However, industries close to end consumers (e.g. food, beverages, cosmetics) are very aware of the importance of adequately communicating risk to the public and the PP will often form part of their communication plans.

In addition, chemicals have always been in the focus of risk management and Cefic (the European Chemical Industry Council), amongst others supports the European Commission's Communication on the PP. Furthermore, precaution and prudence are built into each step of the RA process, as defined by REACH and the OECD.

3. NGO & Civil Society Perception

In general, civil society and NGOs tend to favour a strict version of the PP, reflecting their concern to protect the end user as opposed to business interests. Most NGOs build on the definition of the PP as set out in Principle 15 of the Rio Declaration of 1992, which introduces the PP as a preventative measure against environmental degradation in the face of scientific uncertainty.

An example of the strict stance of many NGOs is Oxfam's argument that products should be allowed on the market only if it has been demonstrated that there are no harmful consequences in doing so. This is a very restrictive interpretation, more restrictive than that laid down in the European Commission Communication of 2000, and is likely to be impractical if applied to real situations. Oxfam UK argued in a briefing paper in 2009[22] that GMO should be put on hold until proven safe, an approach that ignores the scientific impossibility of proving something that does not exist. Science can prove the existence of harmful effects, but proving the complete absence of any risk is an impossibility.

NGOs and civil society promote their strict version of the PP because it is seen as a more suitable process than RA. These stakeholders see the PP as taking possible social and moral effects on the end user more effectively into account, while risk assessments are only carried out for the benefit of industry. To illustrate, Greenpeace has for instance argued that *"the rights of those who stand to be affected by an activity must be prioritised rather than those who stand to benefit from it"*.[23] There is a perception by NGOs and civil society that risk assessments can be somehow altered depending on the emphasised variables.

Civil society tends to advocate use of the PP particularly in cases where the products are destined for perceived "vulnerable" groups in society – children, people with disabilities, the elderly, etc. For example, the European Consumers Organisation (BEUC) has stated that, in relation to the EU Toy Safety Directive, the PP should be invoked because the end consumers are children and so *"the absence of an accident history […] with a certain toy should not be taken as an automatic presumption of a low level of risk"*.[24] Arguably, this reflects a narrower understanding of when the PP should be applied, if sound RA procedures are followed.

22 Oxfam UK, Harnessing Agriculture for Development (2009), p. 24

23 Greenpeace Paper (2006) on Genetically Engineered Brinjal, p. 4

24 BEUC & ANEC statement on the revision of the Toy Safety Directive 2002

4. Role of Media

The media plays a major role in influencing the public perception of risk. The media can affect both the public perception of risk in general and also frame specific safety issues. However, the media is not all-important. Professional networks can also be significant, as can informal networks of friends and acquaintances – the classic "grapevine". People typically trust the goodwill and opinions of family and friends more than any institutional source, while access to decentralised media such as the Internet and social media increases the influence of self-organised networks.

Media coverage often amplifies the public's interest in certain risks but does not create it. A "good story" for the media is one in which public and media interests reinforce each other.

History has shown that potential public health risks are likely to become major stories when the following factors are prominent:

1. Questions of blame;
2. Alleged secrets and attempted "cover-ups";
3. "Human interest" through identifiable heroes, villains, dupes, etc. (as well as victims);
4. Links with existing high-profile issues or personalities;
5. Conflict;
6. Signal value: the story as a portent of further ills (*"What next?"*);
7. Many people exposed to the risk, even if at low levels (*"It could be you!"*);
8. Strong visual impact (e.g. pictures of suffering);
9. Links to sex and/or crime.25

These factors should be kept in mind by regulatory authorities in order to try and prevent media controversies on issues of risk, health and safety from developing. It is important to ensure that certain products do not become stigmatised as a result of public perception in the absence of scientific evidence of harm.

25 Department of Health UK, 1997

Chapter 4: Case Studies

In this chapter, a number of related cases are assessed that help outline underlying logics and/or differences in the interpretation and application of precaution or the precautionary principle (PP).

The cases have been selected on the basis of the following criteria:

- *Scope*: the cases refer to various policy and industrial sectors, hence covering a broad spectrum of experiences;
- *Pertinence*: the cases shed light on the practical relevance of the key elements related to precaution contained in European Commission's Communication on the PP (COM(2000)1 final). In particular, that precautionary actions:
  - be *proportional* to the chosen level of protection;
  - be *non-discriminatory* in their application;
  - be *consistent* with similar measures that have been previously taken;
  - be *based on an examination of the potential benefits and costs* of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis); and
  - *be reviewed*, in the light of new scientific data.
- *Insight*: the analyses seek to explicitly provide insights on how these elements have been taken into consideration, or have been ignored.
- *Relevance*: the cases draw from recent events and regulatory decisions. Also with regard to the discussion of case law in the European Courts, in which "combined" rulings are analysed, reference is made to recent developments in judicial review.

Case Study 1 – The Volcano Ash Cloud Crisis (2010)

Background[26]

Following the eruption of the Icelandic volcano Eyjafjallajökull on 14 April 2010, a cloud of ash, helped by winds, quickly spread across Europe. Since volcanic ash is a recognised threat to aircraft, most European civil aviation authorities closed their airspace. At its height, between 17 and 18 April 2010, 17 EU Member States had a full airspace closure and two

26 The information reported here is available on many Internet websites (newspapers, blogs) and also draws from Alemanno (2010a&b).

were partially closed. At the same time, six non-EU countries were fully closed. The impact of the six-day closure was enormous: more than 100,000 flights were cancelled and about 10 million passengers were unable to travel.

The flying bans were instituted because of fears that the volcanic ash – a mixture of glass, sand, and rock particles – could seriously damage aircraft engines. The national measures were in line with the 2007 guidelines developed by the International Civil Aviation Organization (ICAO), which impose total avoidance of exposure in such instances regardless of ash concentration,[27] as well as with the Volcanic Ash Contingency Plan – EUR Region.[28] Scientific evidence was provided by the Volcanic Ash Advisory Centre (VAAC, linked to the UK Met office)[29] and the European Organisation for the Safety of Air Navigation (EuroControl)[30] implemented the measures. Only a national authority can decide to open or close its national airspace, and there is no EU competence for air traffic management.

After three days of flying bans, all major airlines vocally claimed that authorities had been overly cautious in using a precautionary approach. Facing extreme pressure, EuroControl Member States unanimously agreed to move to a coordinated European approach, based on a more differentiated RA and paving the way for more coordinated decision-making among states, enabling a progressive and coordinated opening of European air space.[31]

Subsequent independent research confirmed that the decision by European civil aviation authorities to ban flying was correct. Scientists report that the ash particles were hard and sharp enough to put aircraft at risk from abrasion on windows and airframes and, more seriously, to melt inside jet engines and clog up cooling ducts – something that could have caused engines to fail and planes to fall from the sky (Gislason, S.R. et al., 2011).

Following this crisis, a new international standard within ICAO for flying in volcanic ash was elaborated in December 2010.[32] This is a globally applicable process to facilitate the management of flight operations into, or near, areas of known or forecast volcanic cloud through the provision of appropriate information to assist in minimising safety risk in

27 http://www.paris.icao.int/news/pdf/9691, notably paragraph 3.4.8.

28 http://www.paris.icao.int/documents_open/files.php?subcategory_id=63.

29 http://www.metoffice.gov.uk/aviation/vaac/.

30 EuroControl is an international organisation with thirty-eight member countries, including the EU Member States. See http://www.eurocontrol.int/.

31 http://ec.europa.eu/unitedkingdom/press/press_releases/2010/volcanic_ash_en.htm.

32 International Civil Aviation Organization, International Volcanic Ash Task Force Guidance Material Management Of Flight Operations With Known Or Forecast Volcanic Cloud Contamination, Preliminary issue - Draft Version 3.1 -19 December 2010.

such operations. The emerging new standard, developed by the Volcanic Ash Task Force (IVATF) represents, first, a shift from a zero-risk policy to a threshold level, which has been rendered possible by the data obtained by engine manufacturers in the aftermath of the crisis. Secondly, it signals a change in the responsibility for the decision to fly in those circumstances, by shifting it from the public authorities to the airline operators. Indeed, the ICAO Draft December 2010 Guidance says: *"For States whose airspace is potentially contaminated by volcanic ash, it is intended that the control measures specified in this document should be sufficient to satisfy their need to be confident in the ability of operators from other States to undertake operations safely into airspace that is known or forecast to be contaminated by volcanic ash; no further action on the part of States whose airspace is potentially contaminated by volcanic ash is intended."*[33]

In essence, the new approach is based on (a) formalising a risk assessment process for use by an operator wishing to conduct such an operation, and (b) an evaluation process for use by that operator's State in assessing whether or not the risk of that operation is minimised to an acceptable level by that operator's use of this process. It is intended that the State of the Operator or State of Registry, as appropriate, would make this determination on behalf of all other Provider States through whose airspace the resultant flight operations would be conducted.

Within a few months of the crisis, a number of measures have been taken at international, EU and national levels to better prepare and face such events in aviation, including the establishment of the Aviation Platform to engage aviation stakeholders in a dialogue as well as an ICAO volcanic ash simulation exercise organised in April 2011.34 The EU Commission issued an Information Note to the Council of Ministers on follow-up and the wider scope of crisis management on 25 March 2011.35

Comments

The eruption of the Eyjafjallajökull volcano can be considered as falling into the category of "emerging catastrophic (or systemic) risks". Typically, we speak of a catastrophic risk when a threat is perceived against the core values or life-sustaining functions of a social system, which calls for urgent remedial action under conditions of uncertainty (Boin, 2010: 233). Besides being seldom (very improbable) and causing very high losses, these catastrophic risks are unexpected and unforeseeable. Above all, they differ from other

33 Appendix F, Point F1.c).

34 http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/11/235&format=HTML&aged=0&language=en. The Commission issued an Information Note to the Council of Ministers on follow-up and the wider scope of crisis management on 25 March 2011 (Council document 8192/11).

35 Council document 8192/11, AVIATION 69.

types of disasters because of the "ignorance" surrounding them: they lack a track record allowing for estimations of the likely probabilities and expected losses. Very often these risks also present a systemic nature, as their epiphany may cause a cascading failure ("domino effect"), which could potentially bring down an entire system or market.

An example of this category of risks is the collapse of critical infrastructures whose incapacity or destruction would destabilise the society and menace security, such as communications, electrical power systems, gas and oil, banking and finance, water supply and transport.

In the case of a volcanic eruption and the related flight ban, the impact of large-scale damages is mainly due to the increase of air passengers, the growing interconnection between people and the intensification of trade and exchanges. The impacts of eruptions that occurred a few decades ago or in more remote areas of the globe remained localised. The Icelandic volcano, by contrast, is on one of the world's busiest air corridors, and the winds blew the ash cloud over the European continent – an extremely densely populated and trade-intensive area.

Because, a clear determination of the frequency and magnitude of this type of risk cannot be foreseen, it is important to establish a governance structure and a decision-making process that allows for the highest predictability possible in cases of crisis. In the context of emerging catastrophic risks, the application of the PP can only occur on a case-by-case basis, after fully estimating costs and benefits of extensive prevention measures.

In this specific case, the (air management) system was clearly not equipped to provide rational decisions. The current, ineffective inter-governmental management system (as opposed to an overtly invoked Single European Sky initiative36) is only one aspect. Risk assessments were based on one single source of evidence (the VAAC) – based on computer modelling, while other sources such as empirical tests carried out by airlines were not taken into account. While the ICAO guidelines put a zero tolerance limit on any concentration of volcanic ash, the European skies were progressively re-opened to flights before the ash cloud was fully dispersed. Questions therefore remain open as to (a) the validity of the RA standards (as defined by the ICAO guideline); (b) the scientific rationale for moving to a preferable differentiated RA approach and shifting the safety threshold only five days after the event; and (c) the role played by (implicit or explicit) cost-benefit analyses in the decision to impose and then progressively remove the ban. It is interesting to note the pragmatism shown by the European Commission in addressing the crisis deadlock during the most critical days, while keeping safety as the first priority and in spite of a precautionary risk management model in place.37

36 http://ec.europa.eu/transport/air/single_european_sky/single_european_sky_en.htm.

37 http://ec.europa.eu/unitedkingdom/press/press_releases/2010/volcanic_ash_en.htm.

The Eyjafjallajökull volcano case highlights not only the challenges for public authorities in instances of managing crisis, but also the role of individual economic operators in ensuring an effective internal management of the risks they incur. A worldwide logistics enterprise is reported to have successfully coped with the volcano ash crisis by quickly redirecting air freight bound from Asia to Europe to Istanbul, Turkey and then loading it onto trucks for delivery to its final destination.38 Examples of this kind have remained an exception, and one of the lessons to draw from the ash cloud case is the need for each actor in the system to take responsibility for the situation.

Case Study 2 – The European Commission BPA Directive (2011)

Background

Bisphenol A (BPA) is an industrial chemical widely used in a number of common products to make the plastic rigid and shatterproof. Tiny doses are found in virtually all plastic baby bottles, sports bottles, food, drinks containers and cans on the market today.

BPA has been the subject of scientific attention and public debate worldwide. As an endocrine disrupter, research through animal testing suggests that even low BPA exposure levels are associated with a wide range of adverse health effects. These may cause developmental problems, including early puberty, changes in the prostate gland and behavioural changes. Exposure to BPA is mainly through the diet, as small amounts of BPA contained in polycarbonate plastics can potentially leach out from food containers and bottles and be ingested. Long-term exposure to low doses of BPA could cause chronic toxicity, especially for newborns and young children.

Harmonised EU rules on plastic food contact materials are laid down by Commission Directive 2002/72/EC. A specific migration limit (SML) of 3 mg BPA per kg food was set down in that Directive. This was amended in 2004 to set a SML(T) of 0.6 mg BPA per kg food.

In 2006, the European Food Safety Authority (EFSA)[39] issued a risk assessment on BPA establishing a temporary tolerable daily intake (TDI) of 0.05mg/kg bodyweight; the SML remained at 0.6mg/kg, maintaining an additional safety factor.[40] In an updated opinion of 2008 addressing the difference between infants and adults, EFSA confirmed that exposure

38 http://www.primo-europe.eu/2010/05/iso-31000-and-the-icelandic-volcano-crisis/.

39 http://www.efsa.europa.eu/en/ceftopics/topic/bisphenol.htm.

40 http://www.efsa.europa.eu/en/efsajournal/pub/428.htm.

to BPA by both categories of population was well below the established TDI. It is believed that the average daily exposure to BPA is well below the level required to exceed the TDI.[41]

International Overview

The measures taken in three non-European OECD countries concerning the use of BPA are briefly summarised below.

CANADA

As a part of the Chemicals Management Plan, in April 2008 Health Canada concluded that there was sufficient margin of safety indicating no adverse health effects from using BPA, with the exception of formula-fed infants. Despite the limited risk, Health Canada proposed the classification of the chemical as *"toxic to human health and the environment"*.[42] The federal government banned BPA in September 2010 and added BPA to Canada's toxic substances list in October of that year.[43]

JAPAN

Japan has taken no regulatory action on BPA. Significant reduction in BPA-exposure levels has been achieved thanks to voluntary measures taken by industry. Acting upon public concern with BPA, the canning industry replaced their BPA-containing epoxy resin can liners with BPA-free PET (polyethylene terephthalate) in many of their products between 1998 and 2003. Alternative measures included switching to a different epoxy lining. As a result of these changes, Japanese risk assessors have found that virtually no BPA is detectable in canned foods or drinks, and blood levels of BPA in people have declined dramatically (50 % in one study).[44]

THE UNITED STATES

Like the EFSA, the US Food and Drug Administration (FDA) does not consider the use of BPA in food packaging as unsafe. In an update issued in January 2010, nonetheless, the FDA signalled *"some concern about the potential effects of BPA on the brain, behaviour*

41 http://www.efsa.europa.eu/en/efsajournal/pub/759.htm.

42 http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=6FA54372-1.

43 On the Canadian case, see Scott, D.N. (2009), "Testing toxicity: Proof and precaution in Canada's Chemicals Management Plan", in Review of European Community & International Environmental Law, Vol. 18/1, pp.59-76); and Vandenberg, L. (2009), "Exposure to bisphenol A in Canada: invoking the precautionary principle", in Canadian Medical Association Journal, at http://canadianmedicaljournal.ca/cgi/rapidpdf/cmaj.101408v1

44 http://www.ewg.org/node/20938.

and prostate gland in foetuses and young children"[45], similar to conclusions by the National Toxicology Program.[46] Accordingly, FDA announced its support for substitution and exposure minimisation measures, a more robust regulatory framework for BPA oversight and further scientific research. The US Environmental Protection Agency (EPA) launched a programme in March 2010 to assess the environmental effects of BPA in waters, to collect test data and to reduce exposure to the chemical.[47] The US Department of Health & Human Services released information to help parents to reduce children's BPA exposure. Discussion is ongoing in the Senate on whether to act.[48] While California decided not to place BPA on the State's list of chemicals believed to cause reproductive harm,[49] a number of US jurisdictions have banned or restricted the use of BPA.[50]

The Commission Directive of 2011

In March 2010, Denmark decided to temporarily ban the use of BPA for the manufacture of plastic materials in contact with food intended for children aged 0-3. The decision followed a risk assessment carried out by the National Food Institute at the Technical University of Denmark. In July 2010, France also opted for a temporary prohibition for the manufacture, import, export and placing on the market of feeding bottles containing BPA. The French Government substantiated its safeguard measure with two opinions issued by the French Food Safety Authority (AFSSA) in January and June 2010, and a report published by the National Institute of Health and Medical Research (INSERM) in June 2010.

The Commission asked EFSA for an evaluation of the safety of BPA, taking into account 800 scientific studies which had been carried out on the substance. EFSA's statement was published in September 2010 and concluded that the TDI for BPA of 0.05mg/kg bodyweight per day did not require adjustment in the light of the studies. One member of the panel nonetheless expressed the minority opinion that the value should become a temporary TDI to reflect remaining uncertainties.[51]

45 http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm197739.htm.

46 http://www.niehs.nih.gov/news/media/questions/sya-bpa.cfm.

47 http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/bpa_action_plan.pdf.

48 http://www.nytimes.com/gwire/2010/08/13/13greenwire-sen-feinstein-vows-senate-vote-on-bpa-measure-55451.html.

49 http://www.foodproductiondaily.com/Quality-Safety/California-finally-rejects-bisphenol-A-ban.

50 They include Connecticut, Maine, Maryland, Minnesota, Vermont, Washington State and Wisconsin, together with three counties in New York State and the City of Chicago.

51 http://www.efsa.europa.eu/en/press/news/cef100930.htm; http://www.efsa.europa.eu/en/scdocs/scdoc/1829.htm. See also Alemanno, A. (2010), "The fabulous destiny of Bisphenol A (BPA)", in Eurpean Journal of Risk Regulation, Vol.4/2010, pp.399-402.

In the light of the uncertainty noted in the EFSA opinion, in the framework of the comitology procedure, the Commission presented two options aimed at minimising infants' exposure to BPA. At the end of November 2010, the Commission presented its formal proposal for a vote in the Standing Committee on the Food Chain and Animal Health (SCoFCAH), which adopted it by qualified majority.

The resulting Commission Directive 2011/8/EU, prohibiting the use of BPA in baby bottles made of polycarbonate, entered into force in February 2011. Member States had 15 days to transpose it, the ban of BPA in baby bottles made of polycarbonate being effective from 1 March 2011. From 1 June 2011, the ban also covered the marketing and import of baby bottles containing BPA. The precautionary principle is one of the legal bases explicitly used for the adoption of the Directive (see its Recitals 16 and 17).

In presenting the Directive, Commissioner John Dalli, who is in charge of Health and Consumer Policy, said, *"1 March represents a landmark in our efforts to protect better the health of EU citizens, in particular when it comes to our children following the precautionary principle."*[52] The EU ban was backed by a majority of Member States, while four abstained.

The Commission confirmed that the ban is limited to BPA infant feeding bottles and is unlikely to extend to other uses of BPA[53], because the EFSA opinion does not provide any evidence to go further. As part of its activities to support the Commission, the Joint Research Centre (JRC) has launched a study on some 300 baby bottles from EU Member States to assess the nature of their materials, chemicals, and the potential release of substances into them; results are expected by late 2011.[54]

Comments

As outlined above, the Commission is not the only authority opting for a BPA ban on infant feeding bottles. In some of the jurisdictions that banned BPA, governments deviated from the opinion of their institutional scientific bodies. The latter generally recommended no public health actions on the basis of the exposure levels ascertained, while acknowledging the need for further research on infant exposure.

52 http://europa.eu/rapid/pressReleasesAction.do?reference=IP/11/229&format=HTML&aged=0&language=EN&guiLanguage=en.

53 http://www.foodproductiondaily.com/Quality-Safety/No-plans-toextend-bisphenol-A-ban-says-European-Commission.

54 http://ihcp.jrc.ec.europa.eu/our_activities/cons-prod-nutrition/food_contact_materials/jrc-studies-non-polycarbonate-baby-bottles.

THE NOTION OF RISK ACCEPTANCE

Like other so-called endocrine disruptors, reproducible toxicity testing and scientific analysis on BPA is particularly complex and controversial. Disputes arise not only because of scientific uncertainties but also because scientific evidence is interpreted in a variety of ways, as shown in the examples of the differences between the EFSA and the French and Danish scientific bodies. Because of the wide range of possible adverse effects potentially associated with these substances, public opinion is particularly attentive to information and advocacy campaigns. Since BPA may affect the health of foetuses, newborns and infants – a very sensitive issue – regulators seem to be considering public concerns very carefully. While precautionary measures appear to be legitimate from this perspective, it is noteworthy that the decision has *de facto* annulled the notion of "acceptable level of risk" in this case, because considerations on hazard have the upper hand over risk assessment.

A number of remarks, detailed below, can be made with regard to the process through which the Commission opted for the ban – the comitology procedure. They include the issue of substitution, which implies the consideration of alternative benefits as well as ancillary risks and cost; and the issue of weighting cost and benefits (through impact assessment practices) when precaution is invoked. Moreover, transparency is a prerequisite when scientific uncertainty is at stake, and decisions are taken against the background of diverging opinion on scientific arguments.

SUBSTITUTION AND RISK-RISK TRADE-OFF

In Japan, industry has used BPA-free materials for several years. However, it is still not entirely clear that manufacturers can switch to BPA alternatives that are as effective and commercially viable.[55] Considering the recent developments and watching consumers' reactions, retailers have already announced that they will voluntarily remove BPA-containing products from the market in Europe. However, some alternatives are reported to be unsuitable for certain types of foods.[56] As a FAO/WHO joint report of November 2010 noted, *"at present, there appears to be no single replacement for BPA for all food contact applications"*. The report also stressed that *"data on the safety of some of these replacement materials are limited or nonexistent"*.[57] The problem is that manufacturers rushed to switch to BPA alternatives that may not have gone through thorough safety checks. Information gathered from consultation rounds in Scotland and reported in the impact assessment

55 See for example, http://www.washingtonpost.com/wp-dyn/content/article/2010/02/22/AR2010022204830.html.

56 See for example the FAQ page on the German Federal Institute for Risk Evaluation (Bfr), http://www.bfr.bund.de/en/faq/selected_questions_and_answers_on_bisphenol_a_in_baby_bottles_and_baby_bottle_teats-60837.html#topic_49906..

57 http://www.who.int/foodsafety/chem/chemicals/BPA_Summary2010.pdf, p.30.

accompanying the Scottish act transposing Directive 2011/8/EU seems to support this concern. The regulatory impact assessment report indicates that the alternative materials are *"mainly produced in non-EU countries"*[58] – hence subject to risk assessment standards and practices possibly different from the EU's.

Risk regulation literature[59] has illustrated this dilemma, the so-called "risk-risk trade-off", according to which efforts to combat a "target risk" can unintentionally foster increases in "countervailing risks". The Commission does not seem to have taken such an eventuality into account – at least if we refer to the information provided in Directive 2011/8/EU. Recital 14 thereof limits itself to note that the alternatives to BPA *"have to comply with the strict safety requirements set out for food contact materials"* and therefore substitutes may be made for BPA in baby bottles. With probably the exception of glass, there is no definitive indication that the alternative materials are safer and present significant advantages to BPA.

IMPACT ASSESSMENT AND TRANSPARENCY

Because it was adopted under the comitology procedure, and since these types of decisions are not listed in the Commission's Work Programme and hence are not necessarily covered by impact assessment,[60] the decision to ban BPA in baby bottles in the EU has escaped a cost-benefit analysis by the Commission. This appears to contradict two important principles listed by the Commission Communication on the PP justifying the adoption of precautionary measures, namely that the measures must be *"proportional to the chosen level of protection"* and that they must be *"based on an examination of the potential benefits and costs of action or lack of action (including, where appropriate and feasible, an economic cost-benefit analysis)"*.[61]

Case Study 3: Precaution in the EU Case Law

A critical juncture in the consideration of how precaution has been conceived, interpreted and applied at the level of the EU refers to the case law produced by the EU Courts – the General Court (GC, formerly named Court of First Instance, CFI) and the European Court of Justice (ECJ). EU Courts are increasingly called upon to review measures that

58 http://www.legislation.gov.uk/ssi/2011/100/pdfs/ssien_20110100_en.pdf, point 3.9.

59 Graham, J.D. and J.B Wiener (1995), Risk vs. Risk: Tradeoffs in Protecting Health and the Environment, Harvard University Press.

60 As outlined in the Commission Impact Assessment Guidelines, SEC(2009) 92. See also http://ec.europa.eu/governance/impact/which_com_init/which_com_init_en.htm.

61 European Commission (2000), Communication on the precautionary principle, COM(2000) 1 final of 2 February 2000, point 6.3.1. and 6.3.4.

are grounded in scientific data (Alemanno, 2009; Rogers, 2011). In the absence of a single definition of the PP, and in their role as interpreters of the EU Treaty provisions, the EU Courts have stepped in on many occasions to complement and/or rectify decisions taken by the legislator. The European Commission acknowledged in its Communication on the PP (EC, 2000: 15) that *"like other general notions contained in the legislation, such as subsidiarity or proportionality, it is for the decision-makers and ultimately the courts to flesh out the [precautionary] principle."* As a result, *"every legal challenge to national or Community risk regulation has offered, and continues to offer, the Courts the opportunity to refine their case law and shape risk regulation even further, in striking a balance between scientific justification and regulatory discretion."* (Alemanno, 2009: 10).

In the following, considerations on precaution and European case law are crystallised by analysing significant cases through three interpretative lenses:

- the intensity of the judicial review of precautionary measures;
- the role of risk assessment findings in the court's reasoning; and
- the evolution of the proportionality test as applied to precautionary measures.

The Intensity of the Judicial Review of Precautionary Measures

EU Courts are not bound by clear indications in the EU Treaty as to the standard of review that they must apply when scrutinising EU acts. Accordingly, they have applied different degrees of intensity to their judicial review, traditionally opting however for a rather deferential (or limited) standard. In settled case law, the Courts have limited themselves to questions of whether authorities have used their regulatory discretion in an arbitrary or unjustifiable manner. In the Upjohn case of 2000,[62] the ECJ elaborated on the deferential review, holding that *"the EC judicature may not substitute its assessment of the facts for the assessment made by the authority concerned"* when the latter is called upon to make *"complex assessments"*. In such circumstances, *"the EC judicature must restrict itself to examining the accuracy of the findings of fact and law made by the authority concerned and to verifying, in particular, that the action taken by that authority is not vitiated by a manifest error or a misuse of powers and that it did not clearly exceed the bounds of its discretion"*.[63]

Focusing on the example of the *Pfizer* case of 2002, and above all the *Paraquat case* of 2007, this case study highlights the reasoning followed by the Court to move away from such a deferential approach while still scrutinising the Commission procedure. It can be argued that the intrusive character of the Court's review further curtails the discretion of the EU institutions.

62 Case C-120/97, Upjohn Ltd v Licensing Authority and others [1999] ECR 223.

63 All quotations from Upjohn, at 34.

THE PFIZER CASE

BACKGROUND

The CFI ruled on the *Pfizer case*[64] (and the linked *Alpharma case*[65]) in September 2002. The plaintiffs challenged the decision by Denmark to ban the use of virginiamycin, an antibiotic, as a growth promoter in feedstuffs, and Regulation 2821/98 by the Council of Ministers banning the use as feed additives of four antibiotics. Two of them, virginiamycin and bacitracin zinc, were also used to treat human infections, prompting concern that bacterial resistance to the antibiotics might be transferred to humans. Because neither the reality of that risk nor its seriousness could be scientifically established (a conclusion reached by the European Commission's Scientific Committee for Animal Nutrition, SCAN), the Council relied on the PP to justify their prohibition – thereby following the proposal of the Commission. The Commission and the Council relied on the same uncertainty information available to SCAN, but reached a different conclusion.

Two major pharmaceutical corporations challenged the Regulation. At that time, Pfizer Animal Health SA was the only producer of virginiamycin, and Alpharma, the only importer of bacitracin in the EU. Pfizer argued, *inter alia*, the Council made manifest errors of risk assessment and management and misapplied the PP. The Court found no manifest errors and supported the Council's decision.

COMMENTS

In *Pfizer*, the CFI reiterated that it has limited scope to ensure compliance with the conditions under which the PP is to be applied when managing risks. Judicial review is confined to assessing whether EU institutions have committed a *"manifest error"* of appraisal when applying the PP.[66] This deferential standard of review – which *Upjohn* referred to in instances where EU authorities are called upon to make *"complex assessments"* – in *Pfizer* was extended to those situations where EU institutions are *"required to undertake a scientific risk assessment and to evaluate highly complex scientific and technical facts"*.[67]

EU institutions are thereby granted wide discretion, extending to not only their choice of appropriate precautionary measures, but also to the establishment of the facts. It is up to the EU institutions to ascertain whether a situation of scientific uncertainty should

64 Case T-13/99, Pfizer Animal Health v. Council of the European Union, [2002] ECR II-3305.

65 Case T-70/99, Alpharma inv.v Council of the European Union [2002] ECR II-03495.

66 Pfizer, at 166, and the other judgments mentioned there.

67 Pfizer, at 168-169 and 323.

trigger the application of precaution. Accordingly, provided that they do not manifestly err in drawing conclusions from the scientific material, the Court will in principle uphold their decisions, since *"it is not for the Court to assess the merits of either of the scientific points of view argued before it and to substitute its assessment for that of the Community institutions."*[68]

It should however be noted that the CFI showed in *Pfizer* a readiness to switch to a more intrusive judicial review. In *Pfizer*, this meant becoming more involved in the examination of the validity and merits of the scientific arguments adduced by the parties to the dispute. The Court engaged in a *"quasi-scientific debate on the main scientific controversy underlying the legal dispute"* (Alemanno, 2008: 60), which inevitably led it to make an express reference to the quality of the scientific evidence the EU institutions had relied upon. In particular, the CFI held that risk assessment must meet standards of *"excellence, independence and transparency"*.[69] By doing so, the CFI defined the framework within which risk assessment must be conducted.[70] At the same time, it set the necessary condition for allowing its judicial scrutiny. An assessment of such a standard is in fact *"an important procedural guarantee"* enabling the judge to review the adequacy of the scientific assessment used by the decision-makers.[71]

THE PARAQUAT CASE

BACKGROUND

Paraquat is an active substance, a component of one of the three most widely-used herbicides in the world. It acts as a non-selective, broad-spectrum herbicide that is particularly effective against weeds. Paraquat has been banned in 13 countries, including Sweden, Denmark, Austria and Finland. The Commission assessed the use of paraquat in a report and then adopted Directive 2003/112/EC in 2003, authorising conditional use of the substance.

Sweden brought an action for annulment of the 2003 Directive before the CFI, supported by Denmark, Austria and Finland.[72] Sweden alleged, *inter alia*, procedural irregularities in the assessment of paraquat, in particular the Commission's conclusion that there were no indications of neurotoxicity associated with the substance. As in the *Pfizer* case, the

68 Pfizer, at 201.

69 Pfizer, at 172.

70 This is the elaboration of the role of risk assessment in the decision-making, which is outlined in the discussion about the Pfizer/Alpharma case below

71 Pfizer, at 172.

72 Case T-229/04, Sweden v Commission [2007] ECR II-2437.

EU institutions were the defendant. But while the EU had invoked the PP in the *Pfizer* case, Sweden invoked the PP against the EU in the *Paraquat* case. Sweden claimed that the PP should have been applied because of possible links between paraquat and Parkinson's disease.

The CFI agreed with Sweden. It held that the Commission erred its assessment of paraquat, which formed the basis for approving Directive 2003/112/EC. The Court annulled the directive.

COMMENTS

In *Paraquat*, the content of the allegations put forward by Sweden called upon the Court to move away from a mere deferential review and to go into the scientific details of the contested Directive. Sweden pointed in particular to two studies that the Commission assessment considered but had deemed irrelevant and therefore not taken into account, one from Guatemala and the other from France. These suggested levels of exposure for users of paraquat were significantly higher than the acceptable operator exposure level. The Court judged that this made the overall assessment incomplete, and hence to be rejected.

The CFI decision redefined the standard for review. It said that authorities must rely on *"solid"* scientific evidence when taking decisions, instead of merely *"adequate"* evidence, as in *Pfizer*.[73] The Court therefore explored whether the Commission disregarded solid scientific evidence raising doubts about the safety of paraquat. As for the two studies mentioned above, the CFI performed its intrusive review on a procedural basis (Hartmann, 2008: 30ff). It identified significant failures in the scientific evaluation process of the Scientific Committee, most notably a lack of written explanations justifying the Commission's conclusions, particularly with regard to the acceptance or applicability of specific studies and findings.

On the basis of these procedural arguments, the CFI reviewed the scientific evidence, underlying the reasoning of the Scientific Committee and concluded that the studies were solid evidence, and therefore had to be taken into account. If they were taken into account, then the overall assessment raised doubts about the safety of paraquat, leading the Court to conclude that the invocation of the PP was appropriate.

The decision in the *Paraquat* case suggests that the Court's meaning of "solid evidence" is *"the consistency between the scientific findings of the studies used, the evaluation of these findings by the Commission, and the subsequent incorporation of these findings into the final legal act"* (Hartmann, 2008: 34). The type of review carried out by the Court in *Paraquat*

73 Paraquat, at 161, as opposed to Pfizer, at 144.

can be defined as intrusive with respect to the determination of scientific uncertainty, and hence the correctness of invoking the PP. However, the Court remained in the realm of the procedural scrutiny. It did so *"by highlighting inconsistencies between the scientific evidence presented and its evaluation by the Commission; rather than conditioning scientific uncertainty on the existence of contrasting scientific opinions."* As a result, the Court avoided assessing the merit of the scientific evidence brought forward by the Commission (Hartmann, 2008: 35).

It is interesting to note in the *Paraquat* case that the CFI ruled – on the basis of the PP – against a decision that the Commission made. As it has been highlighted (Rogers, 2011), Directive 2003/112/EC required operators using paraquat to set up a product stewardship programme and to report annually to the Commission on the impacts, in recognition of remaining uncertain risks for both human health and the environment in the use of the substance. In addition, the same Directive called upon Member States to report by 2008 at the latest on the results of the product stewardship programme and the risk-mitigation measures, so that a decision could be taken on whether to retain paraquat on the authorised list or not. Such provisions by the Commission clearly reflected the fifth criterion of its Communication on the PP, which establishes that precautionary measures be provisional and be subject to review in the light of new scientific data (EC, 2000: 20-21). However, the Court did not consider the fact that the Commission's proposed legally binding monitoring programme would have resolved some of the scientific uncertainties.

The Role of Risk Assessment Findings in the Court's Reasoning[74]

In two cases – *Artegodan* and *Pfizer/Alpharma* – the courts have scrutinised alleged over-precaution in different ways. Initially struck down by the CFI in the first case, the precautionary measures were eventually saved in both cases. This section investigates the arguments relied upon by the judicature, and considers the role they played in the reasoning of the judges about the way RA should be carried out, and the way it actually was.

THE ARTEGODAN CASE

BACKGROUND

The *Artegodan case*[75] concerned the Commission Decision in 2000 to withdraw its marketing authorisation for certain medications for human use, acting upon the recommendation of the Committee of Pharmaceutical Specialists. Artegodan GmbH, a German laboratory

74 For an historic overview on the origins of risk assessment in the Courts' case law, see Alemanno (2009:11).

75 Joined Cases T-75/00, T-76/00, T-83/00, T-84/00, T-85/00, T132/00, T-137/00, T-141/00, Artegodan GmbH e.a. v Commission [2002] ECR 4945.

whose sole product was caught by this measure, saw its own existence endangered and asked the Community Courts to block the ban, taking into account that the Commission granted it authorisation in 1996.

The CFI granted the reprieve sought by Artegodan, prompting additional petitions from laboratories producing other medications also caught by the measure. The Commission lodged an appeal against eight of the nine CFI orders invoking the application of the PP to justify its 2000 Decision. On appeal, the ECJ found in favour of the Commission request.

COMMENTS

Artegodan is considered among the pivotal rulings by the European Courts in cases of scientific uncertainty, primarily because it formally extended the PP to policy fields other than environmental protection[76] and explicitly ranked it as a *"general principle of the EU law"*.[77]

The importance of the case also lies nonetheless in the examination of risk assessment developed by the Courts, as the ECJ overruled the CFI. The CFI acknowledged that the change of the measures to safeguard health decided by the Commission in 2000 was not supported by new scientific evidence compared to the evidence available in 1996, when the drug's use was approved.

The ECJ rejected the CFI reasoning on grounds the lower court considered only the lack of new scientific data concerning RA when permitting the drugs to stay on the market. The CFI should have also appreciated the changed context in which precaution had to be considered in the field of public health, notably the "mad-cow" and dioxin crises, as well as the developments of the PP in EU decision-making. While both the CFI and the ECJ confirm the view that economic and financial impacts must not take precedence over risk to public health, even if it is uncertain[78], the ECJ ruling in *Artegodan* acknowledged that differences in the level of knowledge relative to risk, of the social acceptability of risk, or indeed (albeit with limits) the simple perception of risk, may lead to divergent decisions – even in the face of similar scientific data.

Artegodan demonstrated that the key element in putting the PP into practice is to determinate the acceptable level of risk (Cazala, 2004: 554). This means that precautionary

76 As stated in Art. 191 (former Art. 174(2)) the EU Treaty.

77 Artegodan, at 184.

78 Case C-183/95 Affish BV v Rijksdienst voor de keuring van Vee en Vlees, [1997], at 43; Case T-70/99 Alpharma v Council of the European Union, [1999], at 152; Case T-74/00 (P)R Artegodan Gmbh v Commission, [2000], at 52; Case C-180/96R United Kingdom v Commission, [1996], at 93.

measures may be challenged on the basis of the procedures underpinning the decision, rather than because the risk has not occurred. That makes it crucial to understand how clear and predictable a procedural framework is for regulatory decisions.

THE PFIZER / ALPHARMA CASES

BACKGROUND

For Background information on the case, see above.

COMMENTS

Unlike in *Artegodan*, in the *Pfizer/Alpharma cases* the CFI sketched out a systematisation of the conditions under which the PP can be invoked under EU law. The Court stressed that both the Commission and the Council enjoyed broad discretion when adopting the contested Regulation, and that judicial review must accordingly be limited.[79] However, such discretion is not absolute, and the CFI for the first time elaborated explicitly on the application of the PP (Vos, 2004: 187). In line with previous case law, the Court defined the PP as follows: *"[...] where there is scientific uncertainty as to the existence or extent of risks to human health, the Community institutions may, by reason of the precautionary principle, take protective measures without having to wait until the reality and seriousness of those risks become fully apparent."*[80] The Court also imposed the condition that *"a public institution can be required to act even before any adverse effects have become apparent"*[81], suggesting that EU institutions may be obliged to apply the PP.

The CFI gave a nod to concern about the potential for abuses in its acknowledgement of the non-binding character of the SCAN's opinion and sought to exclude a "zero-risk" approach (Scott, 2004: 60) by laying out a framework which must guide scientific risk assessment carried out by EU institutions. RA must be entrusted to EU scientific committees, even if this is not specifically required in legislation, except in *"exceptional circumstances"* when EU institutions may rely on alternative scientific evidence. Risk assessment must be based on the *"principles of excellence, independence and transparency"*. The Court placed strong emphasis on the quality of the scientific assessment, finding that the overall goal of EU institutions must be to have precautionary measures which are based on the *"best scientific data available"*. Accordingly, precautionary measures cannot rely on a purely hypothetical

79 Pfizer at 166-170.

80 Pfizer at 139.

81 Pfizer at 444.

approach founded on mere hypotheses, and may be adopted only if the risk appears to be properly backed up by the (albeit inconclusive) scientific studies *"available at the time when the measure is taken"*.[82]

By setting the condition of scientific excellence, the Court made the source of such evidence irrelevant, relying on risk managers to interpret scientific risk assessments and to make a final decision. In the case of virginiamycin, the competent EU scientific committee advised that there was insufficient evidence to justify prohibition. The CFI concluded that the EU Council's decision to ban was nevertheless justified in the interest of protecting human health. Regarding bacitracin zinc, the EU authorities did not even seek advice from a relevant scientific committee before prohibition. However, the Court concluded that scientific knowledge about other similar antibiotics justified a "horizontal approach". In case of scientific uncertainty as to the reality of a risk, however, it is precisely not for scientists to decide whether or not that risk is acceptable for society. This evaluation can only be entrusted to political bodies, and the Court therefore clearly distinguished scientific expertise from political responsibility, noting that *"the members of SCAN, although they have scientific legitimacy, have neither democratic legitimacy nor political responsibilities. Scientific legitimacy is not a sufficient basis for the exercise of public authority."*[83]

The *Pfizer case* seems therefore to demonstrate the unavoidable overlap between the risk assessment and risk management functions. Such a blurred interface clashes with the interpretation by the typical EU risk analysis model, which considers the two functions as clearly distinguishable compartments.[84]

The Evolution of the Proportionality Test as Applied to Precautionary Measures

The principle of proportionality has its origins as a control mechanism over the legality of Member State and EU action (as established in the Treaty). As has been explained (Alemanno, 2009: 52), the proportionality assessment implies *"a judgement on whether an adopted measure, be it of national or Community origin, exceeds the limits of what is appropriate and necessary to achieve the declared objective. Therefore, whenever it is invoked against a national or a Community measure, it serves as a ground against which to verify the legality of a given act."*

Only subsequently has proportionality been codified as a risk management tool. In that context, it is used to challenge a discretionary policy set by a national or EU legislator.

82 Pfizer at 144.

83 Pfizer at 201.

84 As exemplified by the general principles and requirements of food law enshrined in Regulation EC/178/2002. On the critique about a clear-cut separation between risk assessment and risk management, see Alemanno (2008:47ff).

This is also acknowledged by the Commission, whose Communication on the PP set proportionality *"to the chosen level of protection"* as the first criterion to assess measures resulting from the invocation of the PP (EC, 2000: 18). The Commission also included the *"examination of the benefits and costs of action and lack of action"* among the general principles for the application of the PP (that is the fourth criterion listed in the Communication), specifying that this should not be reduced to only carrying out an economic cost-benefit analysis but must include wider, non-economic considerations (EC, 2000: 19).

The analysis of selected case law (*Sandoz*, *Pfizer* and *Gowan*) involving proportionality is interesting, because that principle pertains less to the risk assessment than to the risk management realm. While the previous case studies have focused on how EU Courts have addressed the risk assessment stage, this section complements the analysis by putting emphasis on the judicial review of risk management.

THE SANDOZ CASE

BACKGROUND

The *Sandoz case*[85] of 1983 was triggered by the refusal of authorities in the Netherlands to authorise the sale of muesli bars and beverages that contained added vitamins (A and D in particular), on the ground that the vitamins were dangerous to public health. The muesli bars, which were produced by the Sandoz company, were readily available in Germany and Belgium. In consideration of the EU Treaty provisions,[86] the Dutch authorities requested a preliminary ruling from the ECJ concerning the right of a Member State to ban a product lawfully marketed elsewhere in the Single Market.

While it was accepted that vitamins could be beneficial to health, it was also acknowledged that excessive consumption could be harmful. Scientific uncertainty however remained about the point at which level consumption of vitamins becomes excessive, particularly because vitamins consumed in one source of food might be added to those consumed from a different source.

The ECJ ruled that bans such as the one envisaged by the Dutch authorities were permitted (i.e. proportionate) provided that they were not disguised trade restrictions.[87]

85 Case 174/82, Officier van Justitie v. Sandoz BV, [1983] ECR 2445.

86 At that time, Art. 30 of the EEC Treaty (now Art. 36 TFEU), prohibiting quantitative restrictions on imports from other Member States.

87 Informed by the principle of proportionality, Art. 36 of the TFEU Treaty (formerly Art. 30 of the TEC) allows justified breaches of Article 34 on the basis of human health protection, etc, but not as disguised trade restrictions.

COMMENTS

Although not addressing the PP explicitly, the *Sandoz case* is important because it introduced the notion of proportionality in cases of scientific uncertainty. The Court was not requested to rule on whether the Dutch decree impeded the free movement of goods (i.e. whether it was proportionate or not). The only issue was whether that measure was justified within the meaning of Article 30 of the EC Treaty on the grounds of the protection of health. In its ruling, the Court limited itself to note the actual *"uncertainties inherent in the scientific assessment"*[88] with respect to the absorption of any vitamins. It agreed with the reasoning of the Dutch Government that the harmfulness of the intake of any vitamins in high doses or for a prolonged period of time cannot be ascribed with certainty to a single food. Because the quantity of vitamins absorbed rather depends on the whole nutrition of a person, and in view of the scientific uncertainties, the Court held that the Dutch ban was justified (and hence proportionate) to protect human health.

While referring to the proportionality principle in *Sandoz*, the Court proceeded to the proportionality test with a certain ease. It merely ruled that products are allowed where the addition of vitamins meets *"a real need, especially a technical or nutritional one"*[89] – without further explanation how such a hardly-conceivable need could occur. It is not surprising that *Sandoz* was further revisited (in more stringent terms) in subsequent case law. It is reasonable to reject the idea that a product lawfully marketed in some Member States can be banned in another Member State only on the grounds that it cannot be scientifically proven that there is absolutely no risk attached to it (Lenaerts, 2004).

THE PFIZER CASE

BACKGROUND

For Background information on the case, see above.

COMMENTS

Since *Sandoz*, EU Courts have considered the role played by proportionality in EU risk regulation on several occasions (Lenaerts, 2004), as *Pfizer* demonstrates. The CFI was explicitly asked to deliberate on whether EU authorities had failed to opt for the least onerous measure, instead of requiring withdrawal of the market authorisation of a particular antibiotic.[90]

88 Sandoz, at 17.

89 Sandoz, at 19.

90 Pfizer, at 407.

The Court held that the proportionality test has three legs – assessing whether the adopted measure is (a) suitable or appropriate for attaining the desired goal; (b) the least onerous possible; and (c) causing disadvantages not disproportionate to the goals pursued.[91] For the last leg, the Court ruled that a *"cost-benefit analysis is a particular expression of the principle of proportionality in risk management"*,[92] taking into account that *"the protection of public health [...] must take precedence over economic considerations."*[93] Rogers (2011) notes that *Pfizer* and *Alpharma* were the only cases in which an examination of the costs and benefits of a proposed action was explicitly involved.[94]

As has been remarked,[95] *"on these premises, the balancing activity, imposed by application of the third limb of the principle, between the financial losses suffered as a result of the measure (economic considerations) and the objective sought by the Community (public health) could not but lead the Court to uphold the contested measure."* (Alemanno, 2009: 53) It is the risk assessment phase – and notably one following the conditions previously sketched, the Court argued – that must enable the competent authority to take such risk management decisions.[96]

A consequence of this reasoning is the ECJ ruling in *Commission v Denmark*[97] in 2003. The Court found that the Danish food law (Law 471/1998) systematically prohibited the import of all foodstuffs containing additives such as vitamins and minerals, and therefore was disproportionate. The identification of real risks to public health requires a case-by-case approach.[98]

THE GOWAN CASE

BACKGROUND

The European Commission's Plant Protection Products Directive (PPPD, Directive 2006/134/EC) allowed the marketing of fenarimol, a fungicide, for a period of 18 months for a limited group of crops. Upon recommendation by the Standing Committee on the

91 Pfizer, at 411.

92 Pfizer, at 410.

93 Pfizer, at 456.

94 Rogers (2011) considers 140 cases before 2009 in which the PP played some part, and in some cases a major part.

95 Referring to Pfizer, at 459-460.

96 Pfizer, at 163.

97 Case C-192/01, Commission v Denmark, [2003]

98 Denmark, at 55-56. For a similar conclusion, see Case C-41/02, Commission v Netherlands [2004].

Food Chain and Animal Health, the Commission had originally foreseen unrestricted market authorisation of fenarimol over 10 years. Concerns regarding endocrine disruptors were voiced by several EU Member States during further elaboration of the Commission's first proposal.

In 2008, Gowan, a Portuguese company that triggered the market authorisation procedure for fenarimol, sought the annulment of two Italian decrees complying with the PPPD before the Regional Administrative Court for Law of Lazio (TAR Lazio). Gowan challenged the measures transposing the Directive on the grounds that the Directive itself was illegal. Gowan argued that neither the restrictions on permitted uses nor the drastic reduction of the marketing period were justified in view of favourable scientific studies carried out in the course of the assessment procedure, and the Commission's own original proposal.

TAR Lazio stayed proceedings and asked the ECJ whether the PPPD was valid considering that the technical and scientific assessment carried out by the rapporteur Member State found that the risk arising from the use of fenarimol was acceptable. The ECJ held[99] that, *"given the concerns on the subject of [its] potential endocrine disrupting effects"*, the decision to restrict the use of fenarimol was suitable to achieving the Directive's objectives.[100]

COMMENTS

Gowan has been defined *"the most important risk regulation judgment in recent years."* In it, the PP is considered *"an integral part of the decision-making process leading to the adoption of any measure for the protection of human health"*.[101] Hence, the PP appears *"for the first time [...] to be expressly recognised as a risk management principle, virtually informing the whole EU risk regulatory decision-making across different sectors."* (Alemanno, 2011).

The ECJ reviewed the legality of the PPPD in the light of the principle of legal certainty, the possibility of a manifest error of assessment (i.e. breach of the principle of scientific excellence), the precautionary principle and the principle of proportionality. *Gowan* well illustrates the current struggle within the EU over adopting rational, evidence-based, flexible and precaution-oriented decisions. The ruling is controversial in many respects (Alemanno, 2011). In the following only some aspects related to proportionality are highlighted.

The Court did not rule on Gowan's core challenge – i.e. as to whether and to which extent the Commission was entitled to revisit its initial assessment and proposal (supported by

99 Case C-79/09, Gowan Comércio Internacional e Serviços Lda v. Ministero della Salute, [2010], not yet reported.

100 Gowan, at 83.

101 Gowan, at 74.

the Standing Committee's opinion) *"without stating any reason or scientific justification"*.[102] Between the presentation of the first Commission proposal, authorising fenarimol for seven years, and the adoption of the contested Directive limiting the authorisation of the substance to 18 months, moreover, no new evidence had been produced. Investigating first whether the Commission failed to comply with *"relevant procedural use"*,[103] the Court followed the reasoning applied in *Pfizer*. In *Gowan*, however, the ECJ refrained from imposing on the EU institutions a general duty to provide, when departing from the scientific opinion of its committees, a *"statement of reasons […] of a scientific level at least commensurate with that of the opinion in question"*.[104] As a result, *"the Court is implicitly indicating that it is permissible, in these circumstances, for the Commission to respond to public concern, regardless of its scientific foundation and without the need to state the reasons behind its action"* (Alemanno, 2011). Coming to such a conclusion, the Court interestingly does not continue with the other classic prongs of judicial review – namely, its assessment of the "accuracy" and the "manifest error of appraisal". In other words, the Court carried out an amputated procedural test compared to the standards for review established in *Pfizer*.

The Court deviated from previous case law also with regard to its determination of both the source of "scientific uncertainty" and the timing with which such an uncertainty emerges.[105] While settled case law held that judicial review be *"carried out solely by reference to the elements of fact and of law existing on the date of adoption of the contested decision"*,[106] in *Gowan*, concern about the scientific evidence of the risk of endocrine disruption was raised by a number of Member States only at the risk management stage, when the scientific evaluation process had been concluded. *"In other words, unlike previous cases, the risk managers – not the risk assessors – identified the scientific uncertainty triggering precautionary action. This should have led the Court to investigate whether the scientific uncertainty claim made at the risk management stage could effectively be considered 'scientific', or rather the mere expression of public concern."* (Alemanno, 2011).

Because it held that the PP must be considered as *"an integral part"* of the risk regulatory decision-making[107] and that therefore it is to be fully incorporated therein, the Court broadened even further the already wide discretion attributed to EU authorities when

102 Gowan, at 53.

103 Gowan, at 56.

104 Pfizer, at 199.

105 For a discussion on the source of scientific uncertainty, notably in the context of preliminary rulings as opposed to actions for annulment, see Alemanno (2011).

106 See, e.g., Case T-168/01, GlaxoSmithKline Services Unlimited v Commission, [2006] ECR 2969, which refers to Joined Cases 15/76 and 16/76 France v Commission, [1979] ECR 321, at 7, and Case T-395/94 Atlantic Container Line and Others v Commission, [2002] ECR II-875, at 252.

107 Gowan, at 74.

managing risks. Under such conditions, the proportionality test – a principle for the application of the PP – is merely subsidiary and in any event is hostage of the explicit precedence of public concern over science. *Gowan* not only set a rather low threshold for invoking the PP (the acknowledgment that *"there were still certain concerns"* and that these *"cannot be considered based on purely hypothetical considerations"*).[108]

Above all, it established that the PP can be used with no procedural or substantial constraints by the legislator. As has been commented, *"by failing to counterweight the broadening of EU discretionary powers stemming from the invocation of precaution with an effective judicial scrutiny, [in Gowan] the Court seems ready to surrender its function of gatekeeper of precautionary action."* (Alemanno, 2011).

108 Gowan, at 77 and 78, respectively.

Chapter 5: Conclusions & Recommendations

Conclusions

TRUST, PERCEPTION & COMMUNICATION OF RISK

Trust is the single biggest issue informing the application of the PP today. Even when industry, regulators and decision-makers rely on sound scientific evidence to formulate and justify policy, the public can be reluctant to trust them. This lack of trust results in a situation where the public demands the application of precautionary measures, even where they are not necessary or reasonable.

The issues of perception and communication of risks (as opposed to hazards) are closely linked to this issue of trust. A lack of trust affects the public's perception of particular products and this can be fuelled by poor communication of the risks on the side of industry and regulators.

The PP is increasingly being invoked due to unfavourable public perception of an issue. Product stigmatisation is becoming more commonplace – such stigmatisation often being encouraged and amplified by the media or opinion formers. Similarly, recent ECJ decisions have shown us that the Court is more and more willing to take into account the views of the public, irrespective of the scientific evidence available, and that if the public is concerned about a product, precautionary action is justified.

One of the major implications of such a trend is that there is a tendency to use the PP to justify what in fact has already been framed by public opinion. In other words, political communication has become the key decision factor in the application of the PP.

What is more, it is generally easier to communicate hazard than risk, and the public is much more responsive to hazard. Since all products are potentially harmful, it is difficult to counter the argument that a substance/product is hazardous.

In many cases where a sensitive issue is involved (e.g. the health of children) the notion of "acceptable level of risk" is de facto annulled, because the emphasis is on hazard rather than risk, despite the fact that a risk assessment has been carried out. It should be borne in mind that hazard and risk are not mutually exclusive. The question is, can and should regulators confine their consideration to hazard identification only?

There is a need for regulators to consider how to measure public concern, understand its causes and how to gauge what the public perception of risks and the related management

measures will be. This has to be communicated transparently and objectively among all the actors involved in risk decision-making, and balanced with the best scientific evidence available and the other legitimate factors that need to be considered.

Effective communication of information about hazards, risks, and uncertainties helps to restore public trust and confidence in the competence, independence, and fairness of decisions by regulators and public officials. In turn, this strengthens the legitimacy of government action and helps improve compliance and enforcement.

TEMPORARY NATURE OF PRECAUTIONARY MEASURES

The Commission's Communication on the PP requires precautionary decisions to be provisional pending a reduction in the scientific uncertainty. Therefore, precautionary measures are by definition meant to be temporary. The analysis shows, however, that this has not been adhered to in practice, and this issue of the temporary nature of the PP is yet to be seriously addressed. If authorities have the obligation not to wait for scientific certainties when coping with potential risk of serious and irreversible damage, they also have the obligation to take measures that are proportionate, temporary, and reviewable. Nevertheless, we are currently witnessing a trend towards a systematic recourse to product bans, despite the fact that a ban should be the most seldom and extreme measure. This is prompted by the utopian search for zero-risk or zero-exposure. The knock-on effect of this is that, once a product is banned, there is usually no further investment in R&D to support its future development and marketing. More generally, disproportionate precautionary measures can hamper research and innovation.

SUBSTITUTION AND "RISK/RISK" TRADE-OFF

Any use of precaution within risk management decisions needs to be balanced by the recognition of the importance of proportionality and an understanding of trade-offs between costs and benefits. In general, very little discussion about costs and benefits and risk/risk trade-offs seems to occur when considering whether to invoke the PP and reviewing its application, and there is great potential in addressing such an issue more systematically. For example, in the context of the BPA debate, the fact that no safer alternative to the use of BPA in baby bottles had been identified was virtually ignored when deciding whether or not to impose a ban. This was despite the fact that there is no clarity whatsoever whether alternatives to BPA might invoke other risks.

LEGISLATIVE ISSUES

While there are several pieces of legislation and semi-legislative texts, a single comprehensive legislation laying down the conditions and rules for the application of the PP is missing. The Commission has issued a Communication entirely devoted to the PP together with RA guidelines, impact assessment guidelines and a Communication on the Collection and Use of Expertise. However, there are no clear links between these documents, which results in confusion both conceptually and in daily practice. The Commission Communication on the Collection and Use of Expertise[109] suggests that quality standards for scientific evidence should be used. There is a need for the Commission to enhance its information quality standards and guidelines for EU-level risk assessors, focussing on scientific excellence and scientific method.

When the comitology procedure is invoked (as in the case of the BPA ban), consultation and impact assessment are not mandatory. This is understandable – due to the number of comitology decisions each year, it would be too costly and time-consuming to conduct public consultation and impact assessments for each one. It does, however, mean there is a resulting lack of consultation and transparency in procedural matters and potentially incomplete analysis supporting decision-making.

CASE LAW

The case law of the EU Courts leaves open the question of the role of the judiciary and its primary rationale when reviewing risk management decisions – namely, should the Courts be considering public concern exclusively (and hence applying value-judgements) or directly appraising the validity of science or, again, ensuring a robust and rigorous scrutiny of the administrative processes underpinning precautionary decisions?

In a nutshell, the following points have been observed:

- The Courts have consistently held that the EU institutions are the only legitimate actors to take risk management decisions, and that they have wide discretion in doing so;
- At times, the Courts have shown a tendency to validate the science behind regulatory decisions (*Pfizer* case);
- However, there is no clear pattern here, as the Courts have also on occasion attempted to assess the quality of the scientific evidence considered together with

109 Communication from the Commission on the collection and use of expertise by the Commission: Principles and Guidelines [COM (2002) 713]

the process of the science. The recent judgement in Gowan stands in contrast to this.

- Finally, in recent judgements, the Courts have clearly supported the application of the PP (*Paraquat; Gowan*);

It is worth considering what the outcome would be if a potential BPA case were examined by the EU Courts. If such a case were dealt with by the Courts it might shed new light and give further clarification on the application of the PP.

PRECAUTIONARY PRINCIPLE IN TIMES OF CRISIS

The Volcanic ash case study shows that it will be important in future to ensure rational, evidence-based decisions in times of crisis and emergency. Clearly, the rationality of decision-makers can be affected by the novelty, magnitude and scale of the circumstances. How can this be dealt with? In cases like this, to what extent can responsibility be allocated to individual market operators? It will be important that each actor in the system takes responsibility for the situation. It will also be important to keep such measures temporary. It is clear that current regulatory tools and advice are not sufficient to equip regulators with coherent guidance in times of crisis.

Recommendations

1. LEGISLATION & GUIDELINES

Three options are suggested here:

- The European Commission should seek to integrate the PP Communication with other guidelines, such as guidelines on risk assessment and impact assessments, as mentioned above. Such a consolidating exercise would result in a single binding document which would reduce overlap and increase clarity and legal certainty for all actors involved. A more robust framework will result in more predictable decision making.
- Include conditions in the future comitology framework[110] to make risk impact assessments mandatory for comitology decisions whenever the PP is invoked. This would be in line with the Commission Communication on the PP. Furthermore, the enhanced role of the European Parliament under the Lisbon Treaty offers a

110 Under Artices 290 & 291 of the Lisbon Treaty (TFEU) which give new powers to the Commission of delegated and implementing acts.

privileged opportunity to equip the legislature with an internal (but independent) scientific advisory body, building on the existing experience and expertise of STOA.

- Consider the idea of an "Administrative Procedure Act", which would include consolidated guidelines.

Overall, regulators and courts need to adhere to the best scientific evidence available as the only basis for the governance of risk, even when public opinion is critical. Besides, the PP should only be applied with the aim of mitigating a risk, not hazard. Any use of the PP in risk management needs to consider risks associated with the non-use of a product (e.g. as a consequence of a product ban), as well as risks resulting from the continued use of a product or the use of a substitute product. Cost-benefit analysis and risk/risk trade-off needs to be part of every decision to apply the PP.

2. THE APPLICATION OF THE PRECAUTIONARY PRINCIPLE SHOULD BE PROVISIONAL AND PROPORTIONATE BY DEFINITION

Since there is no absolute scientific certainty, innovation, by definition, leads to new situations that are not necessarily dangerous, although they may be unknown.

If the PP is applied, it should specify the risk that is being addressed, and it should define what knowledge is missing. It should always be borne in mind that an absolute absence of risk can never be proven, and therefore should never be required.

Since the PP is provisional, the restrictions which it applies should be revisited after a set period of time. If the anticipated risks have not emerged after this period (e.g. super-weeds from GMOs), then that aspect of the precautionary restrictions should be lifted.

It is suggested that all precautionary decisions should have a "sunset clause", after which time the rule falls. For example, if after the five-year period the risks have not emerged or the missing scientific data has been produced, there should be an automatic lifting of the precautionary measures. In this regard, decisions based on the PP should be reviewed in the same way as any other ex-post revision of regulation.

In relation to the requirement of proportionality, it is worth bearing in mind the quote *"the dose makes the poison"*, attributed to Paracelsus. The application of the PP should be justified by a specification of the extent and probability of the risk that needs to be avoided and should be applied in a proportional manner accordingly.

3. THE APPLICATION OF THE PRECAUTIONARY PRINCIPLE SHOULD BE SUBJECT TO AN IMPACT ASSESSMENT

An impact assessment of the PP should examine the following issues:

- *The risk/risk trade-off*. If a product is banned, an assumption is made about substitution, but is the alternative significantly better?
- *The risk of irreversibility*. Would the application of the PP close off a branch of science that may have great value in ways yet to be discovered?
- *Effects on trading relationships with major partners*. Europe is not an island and such economic outcomes should be taken into account.
- *Risk for the science base in Europe*. Is there a systemic risk if an important application or class of products is removed?
- *Known risks/unknown risks*. The known risks of regulatory intervention should be compared with the unknown risks to health and safety

4. THE APPLICATION OF THE PRECAUTIONARY PRINCIPLE SHOULD SPECIFY THE DEGREE OF SCIENTIFIC UNCERTAINTY

There is no possibility for absolute scientific certainty, nor can the concept of zero risk be achieved. However, what is possible is a definition of what level of uncertainty can be tolerated. The PP can be applied so long as this accepted level of uncertainty exists – if it no longer exists, the precautionary measures should be removed.

If the PP is to be applied due to gaps in the scientific knowledge, it is vital that these gaps be capable of being proven. The problem to date is that bans have been applied before a negative event has occurred, based only on a fear that such an event might occur. The precautionary action is therefore taken based on a hypothetical risk.

The fact that a "perceived risk" exists should not be sufficient reason to apply the PP. Numerous decisions have been made on the basis of "perceived risk" and there are many cases, including the recent E.coli case in the EU, where the perceived risk has been based on false beliefs.

An example of a system that works in the context of marketing authorisations for medicines is that of pharmacovigilance. Where uncertainty exists regarding the potential (possibly ultra rare) side effects of medicines, pharmacovigilance rules put a continuous screening process in place, so if a negative event should occur, it is reported.

5. COMMUNICATION AND DIALOGUE IS KEY

Industry should increase their efforts to engage in continuous dialogue with consumers, other stakeholders and regulators on the risk of processes and products.

Furthermore, the media should be encouraged to engage in responsible risk communication.

The EU institutions should establish a formal and binding policy statement for effective risk communication in policymaking, in the creation and review of legislation and in the implementation of regulations as well as in the use of PP.

Mandatory guidelines should be developed to describe the scope and nature of information about risks that should be communicated by risks assessors to policymakers, and by policymakers to decision-makers and finally by decision-makers to the public.

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European Risk Forum

The European Risk Forum (ERF) is an expert-led and not-for-profit think tank with the aim of promoting high quality risk assessment and risk management decisions by the EU institutions, and raising the awareness of risk management issues at EU-level.

In order to achieve this, the Forum applies the expertise of a well-established network of experts to "horizontal", cross-sectoral issues. In particular, it addresses regulatory decision-making structures, tools and processes, as well as the risks and benefits of new and emerging technologies, of climate change, and of lifestyle choices.

The Forum believes that:

- High quality risk management decisions should take place within a structured framework that emphasises a rigorous and comprehensive understanding of the need for public policy action (risk assessment), and a transparent assessment of the workability, effectiveness, costs, benefits, and legitimacy of different policy options (risk management);
- Risk management decision-making processes should ensure that outcomes are capable of meeting agreed social objectives in a proportionate manner;
- Risk management decisions should minimise negative, unintended consequences (such as new, unintended risks, economic losses, reduced personal freedoms, or restrictions on consumer choice);
- The way in which risk management decisions are made should be structured, consistent, non-discriminatory, predictable, open, transparent, evidence-based, legitimate, accountable, and, over time, subject to review.

Achieving these goals is, the Forum believes, likely to require extensive use of evidence (especially science); rigorous definitions of policy objectives; clear and comprehensive descriptions and assessments of problems and their underlying causes; realistic understanding of the costs and benefits of policy options; and, extensive consultation.

The Forum works with all of the EU's institutions to promote ideas and debate. Original research is conducted and results are made widely available to opinion-formers and policymakers at EU-level. As an expert group, the Forum brings together multiple sources of evidence (such as the experience of practitioners and policymakers; non-EU good practices; and academic research) to assess issues and to identify new ideas. Indeed, direct engagement with opinion-formers and policymakers, using an extensive programme of conferences, lunches, and roundtables, is a feature of the Forum's work.

The ERF is supported principally by the private sector. The ERF does not seek to promote any specific set of values, ideologies, or interests. Instead it considers high quality risk assessment and risk management decisions as being in the public interest. An advisory group of leading academics supports the ERF's work.

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