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Precaution in Europe: Toward a more realistic assessment

Synthesis

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Claire Weill and Konrad von Moltke wrote this synthesis of the international working group about the European precau-

tionary practice, organised by Iddri on December, 3rd and 4th 2002 in Paris. Acts of the

working group is available in the publication Analyse n°03/2004.

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Precaution in Europe: Towards a More Realistic Assessment

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International debate about the precautionary principle –or the precautionary approach, as some prefer– has matured significantly since it was first presented to unsuspecting trade policy-makers as part of the beef/hormones dispute at the World Trade Organisation (WTO) and subsequently in numerous international trade, health and environmental forums. While some still suspect that it is little more than an excuse for protectionism, the elements of precaution are coming into sharper focus, and with them the beginning of a productive dialogue about its application and its relationship to alternative practices in addressing the uncertainty that is an inevitable consequence of policy-making increasingly reliant for guidance on scientific research.

During the early stages of the debate about the precautionary principle, some advocates and critics alike –assumed that the simple invocation of the principle could settle arguments. It is hardly surprising that this has not proven to be the case. When the debate about precaution began, the principle was deeply embedded in the scientific and administrative structures of the countries invoking it, but many of the practices associated with its application had not yet been clearly spelled out. In the past few years, a steady process of articulation has clarified not only the principle itself but also the conditions of its application. This is to be welcomed. The workshop organized by Iddri in Paris in December 2002 was intended as another contribution to this process. It focused on several aspects of precaution.

The Challenges of Precaution

A number of issues are emerging that will require further attention as the debate about precaution matures.

Cumulative Uncertainty

Large-scale policy decisions, whether domestic or international, always involve a dimension of uncertainty. The problems are never perfectly defined and the consequences of policy options never totally predictable. In situations characterised by the need for precaution, uncertainties tend to accumulate:

- ▶ Uncertainty concerning the state of scientific knowledge
- ▶ Uncertainty about various possible scenarios for future developments
- ▶ Uncertainty relating to the fundamentally novel character of the issues that are being raised, and for which neither philosophical nor religious systems have ready answers: humans have become capable of modifying what is human and of influencing the environment irreversibly at a planetary level.

The Supranational Dimension of Policies

The globalisation of economic relationships and of science and technology as well as the development of globe-spanning systems of information and transport has endowed most of the issues that require precautionary action with an inescapably international dimension.

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Highly Variable Temporal Dimensions

Scientific and technological changes enable the introduction of new practices and the attainment of new objectives at rapid rates. New generations of products enter the market in quick succession, before all of the possible consequences associated with them can be assessed. This process is further accelerated by international trade and investment. The complementary knowledge needed to assess the potential consequences of these innovations develops at a much slower pace. Moreover, some of the issues raised are not susceptible to a science-based response on account of their complexity and their interactions with external environments, factors beyond the ability of any laboratory to test. Finally the consequences of certain innovations may not be identifiable until long after they have been introduced.

Changing Status of Science

The relationship between science and society is not static.

- ▶ Society has new expectations for science, from which it anticipates answers to the problems raised by complex interactions between society and technology, for example, the consequences of changes in consumption patterns or of the human impact on the natural environment.
- ▶ The internal dynamics of the scientific community are also evolving and affect the choice of research topics, funding, goals, control of intellectual property, and the increased availability of scientific information in the public domain and in the media.
- ▶ The lessons to be drawn from these changes are equally uncertain, and these uncertainties affect the organizational structures of the scientific community and the priorities pursued by public research budgets, especially at the European level. The status of those with expertise in public debates has significant consequences for interdisciplinary cooperation and the development of freedom of research.

Consequences

Faced with these new challenges, policy-makers must prepare to take timely steps to ensure that risks threatening either serious or irreversible harm do not become established fact before precautionary measures can be taken. This requires the creation of instruments to assess such possible risks and

procedures for consulting citizens, interest groups (including unions, professionals, and voluntary associations, as well as local authorities).

The institutions that manage risk, such as indemnification funds and insurance schemes, must adjust to these new challenges as well. Their adaptations may include increases in the scope of coverage, arrangements for accelerated indemnification, and steps to prevent the aggravation of damage once risks have materialised. In the broadest perspective, the question is whether public authorities need to redistribute the responsibilities of the various actors, in particular by adjusting liability regimes.

Yet no matter how highly developed the institutions of risk management become, the ultimate responsibility will remain with policy-makers and will depend on their ability to make political decisions in a timely manner.

Tools to Support Decision-making and Management in Relation to Risk

The Process of Consultation

The process of consultation reveals the questions that the public may have as well as its views on risks and their seriousness. Nonetheless the appropriate organization of consultations presents several questions, namely, what procedures to use, how to deal with the issue of representation, and how to ensure that consultations focus on the key issues. Links between forms of public consultation and the access provided to key economic actors must be established to ensure the eventual closure of controversies.

Information

Information on existing knowledge and expert assessments must be provided systematically and reliably. It must also include proposed policy measures and detail the processes of expert consultation that have been used.

Expert Assessment

The dilemma of expert assessment is that while it is essential to address any issue of precaution and is frequently presented as incorporating all the necessary information, it must still be put in a credible policy context that also permits access to alternative points of view. Several layers of accountability are associated

with expert opinions, including the criteria for choosing experts and the extent to which policy-makers must provide a public accounting of the expert opinions they receive and how they use them.

Insurance

Insurance is traditionally an institution that quantifies risks by establishing prices for distributing them within a risk pool. Insurance is confronted by new risks that overwhelm the processes it uses for managing their economic consequences. This in turn shifts an additional element of risk to policy-makers and the public and requires that appropriate institutions ensure that outcomes remain within acceptable parameters.

The Need for a New Policy Culture

It is more than ever necessary to make decisions that are not constrained by a view of the future that holds no alternatives. For this reason, scenarios are developed for policy-makers to situate decisions within a framework that explicitly takes into account the existence of alternative scenarios. In practice some uncertainties are inherent in the scientific response to problems that arise, while others have to do with the range of variability associated with quantitative projections about topics in demography, water resource availability, fossil fuels, and migratory patterns: this variability increases as the period covered by the projections increases or as the data are highly sensitive to unstable processes. One typical example of these uncertainties involves cross-border migrations caused by the degradation of natural resources or by geopolitical insecurity.

Undeniably the degree of complexity of the problems that policy-makers confront today has grown enormously and can be expected to grow further. Consequently policy-makers can no longer rely on experts to provide them with unambiguous policy prescriptions. A significant shift thus downgrades the relative importance of detailed expertise and elevates in importance the pursuit of broad policy visions that permit the contextualisation of policy options.

It is therefore necessary to identify the forces that limit the possibility of a precautionary approach. It makes no difference whether these forces are based on real or perceived factors; they must be addressed on a case-by-case basis. The challenge is to

ensure political accountability so as to maintain a balance between the many competing interests that affect precautionary measures. Policy-makers here must exercise a significant measure of discretion. Nonetheless the structures to ensure their accountability are no different than the structures that apply to decisions with less room for discretion. Just as the precautionary principle is an integral part of the structure of governance, the measures that are available to ensure accountability do not differ from the measures applicable to other decisions. They differ from one country to the next, depending on the specific constitutional balance.

Administrative Procedures

All European countries have highly developed laws and regulations governing administrative procedures. These apply to precautionary measures no less than to other administrative processes. They are designed to ensure that decisions are made in a manner that is firmly grounded in the law and consequently in available expert advice, adequately transparent, with sufficient opportunity for interested parties to be heard. Yet actual practice varies widely from one country to the next; it reflects a range of specific historical influences that have shaped administrative cultures in the different jurisdictions. One of the most characteristic elements of these traditions is the line that separates political oversight and civil service. France has a cabinet system of governance, with a separate administration that enjoys significant autonomy. Ministers are expected to be members of parliament but need not be so. Germany uses “political” civil servants at the highest level of the administration to serve as the hinge between politicians and the civil service. Ministers are almost without exception members of parliament. The United Kingdom has a tradition of virtual anonymity for civil servants. Ministers must be members of one of the Houses of Parliament. In the Netherlands ministers are heads of the administration. They do not need be members of parliament. A similar set of institutional safeguards operates at the European level, originally much influenced by French administrative traditions but subsequently modified to reflect some practices in other member states.

Parliamentary Oversight

All the countries of Europe have some form of parliamentary oversight, but the forms differ widely. The United Kingdom has

the most recent and, by all accounts, the least effective procedures. Germany has highly developed procedures for preliminary negotiation of key administrative actions with parliamentary committees, which also are in a position to monitor budgets very closely. France and the Netherlands lie somewhere in between. In all parliamentary democracies the government requires majority support in parliament to exist—so the control of parliament is the first order of any competent government's business. This clearly limits the ability of parliaments to exercise oversight. The European Parliament has acquired increasing authority, which has focused on budget approval (with obvious implications for oversight) and legislation. In extreme cases, the European Parliament can force the commission to resign but this is hardly likely for the normal exercise of administrative discretion.

Judicial Oversight

The judicial system is an additional layer of oversight, but access to this institution differs widely from country to country as does the organization of judicial procedures. For example, mad cow disease did not lead to any judicial proceedings against administrative authorities in the UK whereas the distribution of tainted blood produced high-profile cases in France. Both countries use courts of general jurisdiction for these purposes but Germany has a system of special courts whose sole function is the review of administrative actions. In all countries, private citizens have access to the courts when they believe that administrative actions have deprived them of their property without just compensation— but the legal doctrines of property differ widely, ranging from the common law traditions of the United Kingdom to the German constitutional stipulation that “property entails societal obligations”, a provision that can justify significant administrative action.

Interest Group Politics

Interest groups have come to play a central role in the formation of public policy in all EU countries. This phenomenon is particularly pronounced at the EU level, where less transparency results in more influence for well-organized interests. The underlying assumption is that interests will be effectively articulated and will contribute to the full ventilation of all aspects of most decisions. This is true in particular of precautionary

measures, where decisive action is to be expected primarily when some interest attains overwhelming saliency—such as forest damage in the case of acid rain in Germany or exposure to lead from leaded gasoline in the United Kingdom— or when no significant interest group opposes some form of precautionary action—as happens quite frequently in matters pertaining to agriculture because all interested parties fear disruption of the tenuous existing balance of interests more than they expect benefits from innovations that promise dramatic increases in productivity.

Public Participation

Public participation is a fundamental process for environmental management at all levels. It is a basic instrument for implementing environmental law, given that environmental quality is the concern of every person and that attempts to limit legal standing by property or geography run very quickly into major problems. Public participation also plays an important role in precautionary action since it establishes an additional forum for accountability over and above the regular institutions of governance. The forms of public participation vary from country to country, but often not as widely as other institutions of governance because the processes are relatively recent, mutually influenced, and have often developed within a framework agreed upon at European level.

Transparency and Freedom of Information

Requirements ensuring the transparency of precautionary decisions facilitate accountability and often form the basis for public participation. Most European countries have administrative traditions that largely protect civil servants from public scrutiny, most pronounced in the United Kingdom but significant everywhere. New (often environmental) rules governing transparency can conflict with these traditions and even encounter a degree of hostility on the part of the policymakers concerned. Some countries—notably France and the Netherlands— have enacted “freedom of information” regulations, but these are not used as extensively as might be imagined and they have been significantly restricted in practice.

This brief overview of accountability for precautionary action in Europe indicates the diversity of relevant institutions and processes. It suggests a significant degree of

accountability can be achieved for important decisions. The variety in practice underlines, however, the difficulties in producing consistent outcomes from one country to the next. This leaves the choice of strategies at the international level: cooperation or segmentation. Cooperation seeks to ensure consistency of outcomes based on common procedures. Segmentation accepts that a degree of variety is inevitable, from some perspectives even desirable, and consequent loss of (economic) efficiency is tolerable as part of the price for open, democratic, and accountable decision-making.

Developing Responses that are Progressive and Never Final

When knowledge is uncertain, policy responses based on it need to be open and subject to review and, if necessary, reversal. Traditional forms of administrative or legislative action are not adapted to these requirements, nor are commercial practices. For example, a decision to delay the introduction of a product is often the same as its abandonment. Under these circumstances it may be argued that substituting one product for another or stopping the use of a new product that is not of high priority may represent a more reasonable alternative than permitting its marketing without adequate information on associated risks.

Precautionary practice is reflective by its very nature. Asking whether the consequences of a decision will be acceptable requires confronting a wide range of issues relating to the product chain, to administrative oversight and to the management of industrial installations. This approach can readily extend to a full range of public and private actions.

Public Accountability and Private Liability

Liability is the functional equivalent of accountability in the private sector. The actions of private enterprises are subject to the law and to the control of those who participate in it. Even though there may be no legal requirement for precautionary action to define or limit the actions of private actors, responsibility for these actions remains undiminished. Even compliance with clear legal prescriptions may not absolve a private actor

from liability. Consequently the relationship between precaution and liability is an important issue that needs to be explored much more carefully.

The example of asbestos is particularly illuminating in this regard. The public authorities were clearly dilatory in their response to the risks associated with asbestos. But the private companies that produced and distributed asbestos products have faced a crushing liability from their actions—frequently in part because they disregarded information available to them about the risks. Many companies have gone out of business because of their asbestos activities—the ultimate penalty for a private enterprise.

The European Level

Precaution poses particular challenges at the European—as opposed to the broader international—level. The integration achieved between the countries of the European Union necessarily means that risks are also increasingly European in character. Precautionary decisions taken by the authorities in one country about a possible risk almost inevitably result in a European process to review the decision, identify its implications for other member states and consider whether European measures are necessary to ensure the smooth functioning of European policies.

European action on precaution is generally not itself precautionary, but it occurs in response to precautionary action taken by one or more member states. Only rarely is the European Union itself the level of primary precautionary action. In reviewing precautionary measures by member states, however, European institutions inevitably become a forum in which the appropriateness of these measures is considered. Under certain circumstances European institutions, especially the European Commission, have the authority to initiate steps to reverse precautionary measures as not reflecting a European consensus. In other circumstances the European institutions can lead to the extension of precautionary measures to all member states.

Issues of competence are critical in this regard. For matters that fall into the exclusive competence of the member states, European institutions exercise a very limited form of review to ensure compatibility with the provisions of the treaties, for example, to

avoid hidden barriers to the common market. In matters of shared competence, the initiative nonetheless still lies most often with a member state, since European institutions cannot generally initiate the action. In matters within the exclusive competence of the European Union, precautionary action must, at least in theory, be initiated or sanctioned at the European level. In practice, individual member states still play a critical role.

The relationship between precaution and the multilateral trade regime represents a particular problem from the European perspective. Member states are for the most part the primary forum for precautionary action; yet the European Union has exclusive competence for commercial policy and negotiates at the WTO for all member states. It must consequently defend precautionary actions that it did not itself originate.

SYNTHESIS

The Iddri Workshop

The papers that are reproduced here were presented at the Iddri workshop on European precautionary practice. They highlight some of the issues that need to be taken into consideration in applying the precautionary principle, in particular in an international context.

Claude Henry addresses the question of when available scientific information suffices to justify action. He does so by considering two cases where the critical point was clearly missed: asbestos and antibiotics as growth promoters in animal husbandry. He emphasizes the importance of the Intergovernmental Panel on Climate Change (IPCC) as an international institution designed to avoid repeating those mistakes.

Hervé le Treut is an active participant in the IPCC process and describes some of the features that contribute to its effectiveness. He emphasizes the difficulty at addressing issues that are global in character and where winners and losers over time are difficult to identify but also points out that these two characteristics allowed the creation of this institution, which organises expertise on climate change at an international level.

Ulrich Müller-Herold considers the role of researchers themselves in the assessment process in relation, for example, to epidemiology or toxicology. He discusses the continuing difficulties in establishing precautionary policies for new chemicals and how these problems reflect the limitations of estab-

lished methodologies and the difficulties in agreeing on new ones. He underlines the tensions that persist between experimental scientists and those whose use modeling, and hence probabilistic assessments.

Monique Eloit takes a closer look at the French food safety agency (AFSSA) and the legislation establishing it, with particular concern for the relationship between science and decision-making.

Gérard Pascal reviews the development of policy-makers' interest in science in Europe and the resulting shifts in balance between the research function and the policy development function. He asks whether an equilibrium between them exists that may at some point be identified and considers the embryonic states of development of internationalized forms of European expertise.

Mae-Wan Ho and Peter Saunders approach these issues from a perspective more strongly informed by advocacy. They use tobacco and the bovine growth hormone (bovine somatotropin or BST) that increases milk production as examples of risk identification and extend this argument to genetically modified organisms. They underline the importance of developing collective, public structures of decision-making related to risk and precaution and stress the distinction between precautionary action before a possible event and the subsequent assignment of liability through the judicial process.

Axel Conrads describes the harsh political response to an agency that failed to exercise precaution: the dismantling of the Federal Health Office (*Bundesgesundheitsamt*) in Germany after its tardy response to early evidence of contamination of blood transfusions by the HIV virus. He underlines the importance of maintaining scientific standards and independence in the face of strong pressure from—and much higher salaries in—the private sector. The paper highlights the importance of agency leadership and the need to establish appropriate relationships with policy-makers, in this instance the minister, and a possible structure of parliamentary oversight.

Marie-Laure Tanon looks at the EU directive on environmental liability, which resulted from a process that took many years. She discusses the liability regime introduced and its limits, the definition of damage used in the directive and its relation to matters that it does not clearly classify, such as biodiversity and its preservation and appropriate restoration. She outlines the key issues of the compromise that was finally reached in June

2003 and discusses the degree to which the directive breaks with the principle of the level playing field. She explains why insurance coverage was not required and why contractual solutions continue to be sought for this issue.

Taken together these contributions provide an introduction to the current state of the European debate concerning precaution.

It is characterized by increasing attention to the institutional and organizational aspects of a topic that appeared initially to be more a matter of explaining how public authorities in Europe reach certain decisions. In the process it has become clear that a better understanding of these processes is needed and that certain aspects must be more clearly defined and better institutionalized.

The Essence of the Precautionary Principle

Claude Henry

CNRS, France

The precautionary principle is formulated in many different ways. However, the differences are not of a fundamental nature. What is fundamental in the principle —i.e. the recognition that decisions must be taken on the basis of uncertain (also called ambiguous) scientific information— is also common to all formulations. But what is meant exactly by uncertain scientific information and what makes it an acceptable basis for decision? Any non-falsified hypothesis might not be deemed acceptable in this sense.

We try to identify what makes an uncertain piece of scientific information acceptable in a decision-making process, drawing from the asbestos, antibiotics as growth promoters and climate change decision processes.

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How Can Expert Advice be Organised on an International Scale? The Case of IPCC

Hervé Le Treut

Laboratoire de météorologie dynamique, CNRS, France

The Intergovernmental Panel on Climate Change (IPCC) is probably the best current example of the international development of expertise on a given subject. There are several reasons for its success. First, an indisputable corpus of scientific data exists to demonstrate the increased atmospheric concentrations of carbon dioxide and other “greenhouse” gases, such as methane, since the beginning of the industrial era. Moreover, climate change is a global problem and it is not yet possible to determine the potential winners and losers. Both these constraint facilitate the participation of experts from different countries. Although the extent of the consequences to be expected from the atmospheric modifications underway must

still be assessed, this corpus constitutes an extremely solid base that has made it possible to begin the process of expert evaluation and to create a body responsible for organising it on an international level. The mandates conferred on the IPCC by the World Meteorologic Organisation and United Nations Environment Program are very clear: by its regular reporting of the published scientific results, the activity of the IPCC is distinguished from that of research laboratories; it must also remain apart from the negotiation process. IPCC’s reports are developed according to a specific process that includes different levels of drafting, editing, and review by experts and governments (review of summaries for policy-makers). The success of the IPCC process, at least for Working Group 1, was possible only because a large, well-structured international scientific community already existed. Nonetheless this system is (of course) not defect-free and there is still room for improvement (the example used here is that of Working Group 1, but these comments can be applied, with only several slight changes, for the other two groups). First, there remain problems related to the dissemination of information. For example, the summaries for policy-makers result from the selection and then the extreme condensation of information from the body of the report, and it turns out that these choices can very strongly slant or even confound the message for the political policy-makers. This final phase of the process must therefore be carefully monitored. Another problem is the need to improve the qualification and joint presentation of uncertainties that are by nature very different: we have far to go. Finally, the reports must treat and describe the minority scientific opinions more fully.

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Type II Ambiguity and Precautionary Screening with Respect to Large-scale Chemical Threats in the Environment

Ulrich Müller-Herold

ETH, Switzerland

The use of the precautionary principle as a tool of risk management is very controversial today on both sides of the Atlantic, and especially among scientific experts. These debates oppose the partisans of an analysis of risk factors before widespread exposure to those who prefer an analysis of any suspected effects *a posteriori*. A further problem is that ambiguities appear at several stages of risk assessments. Sociopolitical ambiguity is related to the variety of legitimate interpretations of identical observations and identical data. Another, which we call here type-II ambiguity, lies in the difficulty of identifying in advance the disciplines that should coordinate the process of multidisciplinary research. In standard assessments of the harmful environmental effects of chemical products, toxicologists and ecotoxicologists intervene at the end of the process; they communicate the study conclusions and thus suggest the measures to be taken. This process does not, however, consider either the infinity of possible biological effects of these chemicals on organisms and ecosystems, or the complexity caused by the indeterminable diversity of the environment itself. All of the actors in this field, public and private, want risk assessment procedures to be overhauled, but few efforts have been made to develop more effective tools of analysis. The acceleration of marketing approvals and the very long time scale of the damage they can cause mean that a precautionary approach is urgently needed; it must include a prescreening of products before they are marketed. The author proposes to estimate the extent of endangerment of the environment by a given product, by analysing three parameters with methods from environmental chemistry: the product's persistence in the environment, its potential for bioaccumulation and its mobility. The challenge lies in finding reliable criteria for the preselection of products with

rapidly accessible parameters. At least for now, chemistry appears most appropriate for this purpose. The development of toxicogenomics, nonetheless, may again modify the situation and lead to a type of mixed responsibility for the preselection of these chemical products.

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The AFSSA (French Food Safety Agency): Food for Thought After Four Years

Monique Eloit

AFSSA, France

The French Food Safety Agency (AFSSA), created in 1998, is part of an overall system to strengthen health surveillance and the monitoring of health security in the areas of food, drugs, and the environment. AFSSA is responsible for three essential missions covering the entire chain of production of food intended for human consumption: risk assessment, research, and scientific and technical support. Four years after the agency's establishment, our experience provides some basis for consideration of the questions common to all of the agencies responsible in whole or in part for assessing food-related health risks, agencies now being created in nearly every European country. First, the legislature, in creating AFSSA, did not choose to separate the spheres of risk assessment and risk management, but rather to articulate them by clearly identifying the responsibilities of each. Accordingly, the Agency issues opinions and recommendations, which cover the exercise of public health police powers; it is consulted on all regulatory projects related to food safety; and it must receive all of the information and data collected during administrative surveillance and controls in this area. Second, although AFSSA is not an independent authority but a public administrative establishment supervised by three ministries (agriculture, health, consumer affairs), the statute includes several provisions that enable the agency to obtain, organise and make public independent scientific expert advice (public budget, opinions released to

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the public, agenda control, rules governing the organization of expert advisory opinions, public disclosure statements, methods for choosing experts, etc.). Finally, although the various aspects that must be taken into account (public health and also political, diplomatic, media-related, economic and legal dimensions) to assess the Agency's work make this a difficult exercise, it is essential to the development of such agencies. Only in this way can we prevent and correct the flaws and weaknesses in the European system now under construction.

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Relations Between Scientific Experts and Public Policy-makers in the Area of Food

G rard Pascal

INRA, France

Twenty-five years ago, the work of experts about the health aspects of human food were essentially devoid of any interest for policy-makers, at either the national or European levels. The health crises that have struck Europe and its member states and the questions raised by genetically modified organisms have progressively reversed this attitude: exchanges between experts and policy-makers have multiplied, and the assessments of experts have become extremely important in the eyes of all –citizens, media, policy-makers, and companies. At the same time, reforms have reorganised the procedures and use of scientific expertise to assess the health risks associated with human food. France created its national food safety agency in 1998 with as one of its principal missions the organisation of independent risk assessments. At the European level, expert committees were regrouped in 1997 into a Directorate-General uninvolved with the food industries. Until mid-2003, these committees were headed by the Scientific Steering Committee, which was also responsible for making proposals to harmonise the methodologies used for food and health risk assessments. Once the relationships between scientific experts and policy-makers are formalised,

these proposals may also be applied to the scientific committees of the European Union and of the Codex Alimentarius, thus magnifying the international impact of the European reforms in this area. This reorganisation has also allowed reflection on the independence and transparency of the activities of scientific experts and led to the creation of a European Food Safety Authority in 2002. One of its first tasks must be to define the conditions for the national agencies to participate in its work.

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Science and the Precautionary Principle

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The precautionary principle states that we must not develop or use a technology until we are convinced that it is safe. It has encountered fierce opposition, especially in the United States, where it is often presented as opposition to progress, sanctification of unscientific prejudice, and a pretext for protectionism. Its opponents want to resolve disagreements in this domain in court. Such a choice allows at most an individual case-by-case assessment of any damage and that only after the fact, when the damage is done. The examples of smoking and bovine growth hormone (bovine somatotropin or BST) refute the arguments against the precautionary principle described above. If this principle had been applied to tobacco when its use began, it would not have prevented either its diffusion or its use for approximately four hundred years –until the first epidemiologic findings appeared. Applied at that point, it would have prevented the deaths of many thousands, perhaps millions, of persons. Moreover, although the danger of the BST hormone can be demonstrated only with test groups, well-founded bases for serious concern are plain. To the extent that this hormone benefits no one but its manufacturers, countries must be able to decide for themselves if the risk is acceptable. Similarly, there is evidence

strongly suggesting that genetically modified organisms are hazardous. The genome that is being manipulated is far from well understood and thus far from controllable. Genetic engineering is creating new combinations of genes likely to spread throughout the environment much more rapidly than natural species and to cross the species barrier. Some genetically modified plants contain toxins that may be allergens for humans. Finally, the first cancer cases have been identified among the «successes» of gene therapy. The precautionary principle, rather than unscientific, requires more research in order to prove the safety of new products and processes. It is unsurprising that the precautionary principle is contested for it places this responsibility—and its cost—on those who stand to profit from each technological advance.

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The Dismantling of the German Federal Health Agency: A Case of (Failed) Institutional Precaution

Axels Conrads

Ecologic, Germany

The contaminated blood scandal erupted in Germany in 1993 when the press revealed that 373 persons had been infected with the HIV virus during blood transfusions since 1985. The Federal Health Office (BGA) was disbanded, to be reorganised in 1994. The central structure that administered the seven independent scientific institutes, the administrative organ was abolished, and the institutes themselves became federal agencies. Nonetheless, they continued to be controlled at the ministerial level. An inquiry board appointed by the parliament identified the failures and dysfunctions in the national Ministry of Health and in the Federal Health Office. Specifically, the BGA chose to maintain a constant quantity of blood available, without insisting on its treatment, thereby protecting both non-profit producers and the commercial companies involved. At the conclusion of the investigation, these malfunctions were attributed to the incompetence and weakness of the Agency's

administrators, to the lack of the transmission of information from the institutes, and to the role that private and political interests played in these decisions. The Office president focused principally on his outside activities, more lucrative than his official function. The Ministry, which had not considered it necessary to strengthen its resources against AIDS, was held responsible for its decisions, or absence of decisions, including the action the BGA had begun to plan. The BGA reforms aimed especially at reinforcing the circulation of information within the government and clarifying the responsibilities of each agency. It did not seek, however, to separate public from private interests at the highest echelons of public decision making. The inquiry board made the following recommendations. One key to the system should be the presence of independent heads for the institutes, responsible for organising expert opinions and for guaranteeing their independence from economic and political pressure. They should simultaneously be good scientists and good administrators, able to deal with extremely vast quantities of very heterogeneous data. In addition, patients should be involved in a participatory process. Finally, a parliamentary body should be established to safeguard the independence of the Office's evaluations and the implementation of the precautionary principle.

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The Directive on Environmental Liability

Marie-Laure Tanon

Environment Ministry, France

The proposal for a directive on environmental liability adopted by the European Commission in January 2002 was intended to extend the liability of all of those involved in "pure ecological damage", currently the area of environmental harm for which the public law of member states provides the fewest remedies. This project is ambitious but also reductive, leaving aside as it does damage to persons and property and economic damage. The economic field covered is limited by several important exclusions: diffuse pollution, maritime transportation and activities involv-

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ing atomic radiation. Moreover, a detailed analysis shows that the directive will be difficult to implement, its effect on economic operators limited and its dissuasive power unfortunately low. Although the directive starts by energetically implementing the “polluter pays” principle and announcing a principle of unlimited liability, regardless of fault, for all activities regulated by community environmental law, this ambition is strongly attenuated by the many exemptions from liability. These involve essentially all pollutant emissions and events authorized by regulation or an individual license as well as development risks; moreover, the burden of proof will lie most especially on public authorities. The proposal for a directive places another very heavy responsibility on these authorities, secondarily liable in all of the cases—numerous because of the exemptions—in which liability cannot be either identified or implemented. The political agreement reached in June 2003 at the Council of Ministers of the Environment deleted this secondary liability from the text. Nonetheless, implementation of this directive confronts authorities with a huge task. Moreover, exemptions for administrative authorisations and development risk are referred back to the law of member states, a decision hardly conducive to a level European playing field. Finally, the new version still does not require insurance.

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Les pratiques européennes de précaution

Eds. : Konrad von Moltke (IISD), Claire Weill (Iddri)

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