PUBLIC DECISION-MAKING IN THE FACE OF UNCERTAINTY

Clarifying the rules, improving the tools

COMITÉ de la PRÉVENTION et de la PRÉCAUTION

Composition of the CPP

President

Mr. Alain GRIMFELD, *UPMC, Paris 6*

Members

Mr. Claude ALZIEU, *IFREMER, Nantes*
Dr. Denis BARD (vice president), *EHESP Rennes*
Mr. Frédéric Yves BOIS, *INERIS, Verneuil en Halatte*
Mr. Patrick BROCHARD, *Bordeaux Segalen University, Bordeaux*
Ms Sylvaine CORDIER, *INSERM, Rennes*
Mr. François DANIELLOU, *Bordeaux Institute of Technology, Bordeaux*
Prof. Jacques FONTAN, *UPS, Toulouse*
Prof. Jean-Marie HAGUENOER, *Faculty of Pharmacy, Lille*
Mr. Philippe HARTEMANN, *Faculty of Medicine, Nancy*
Mr. Philippe HUBERT, *INERIS, Verneuil en Halatte*
Mr. Reza LAHIDJI, *GREGHEC, Paris*
Prof. Armand LATTES, *UPS, Toulouse*
Ms Christine NOIVILLE, *CNRS, University of Paris Panthéon Sorbonne, Paris*
Mr. Jacques VARET, *BRGM, Orléans*
Dr. Philippe VERGER, INRA, *Paris*
Dr. Pierre VERGER, *INSERM, Marseille*

Secretariat and Edition

Ministry of Ecology, Sustainable Development and Energy
Directorate of Research and Innovation
Environmental Risk Prevention and Public Health Management Unit
Ms Sylvie CHARRON
Mr Dominique THIERRY

The authors wish to thank the persons who have been heared during the inquiry concerning public decision making in the face of uncertainty:

M. Dominique BUREAU *(Ministère de l'Écologie, du Développement durable et de l'Énergie)*

M. Bernard CHEVASSUS-AU-LOUIS *(Ministère de l'Alimentation, de l'Agriculture et de la Pêche)*

M. Didier HOUSSIN *(Direction Générale de la Santé)*

M. Pierre-Benoît JOLY *(Institut Francilien « Recherche, Innovation, Société »)*

Committee for Prevention and Precaution

Public decision-making in the face of uncertainty

clarifying the rules, improving the tools

Paris, march 2010

MINISTRY OF ECOLOGY, SUSTAINABLE DEVELOPMENT AND ENERGY

First edition march 2010

English edition june 2012

CONTENTS

Preface and clarification of terms*

The opinions it issues on risks in the field of environmental health require the Committee for Prevention and Precaution to focus regularly on "public decision-making in situations of uncertainty". Beyond this specific perspective, the Committee has in the past examined general questions related to this theme, such as the precautionary principle or the role of expertise in risk assessment. In 2008, the Committee decided to approach this topic in its entirety, by characterizing the different forms of uncertainty that public officials may face in their task of protecting citizens and the environment and identifying ways to improve the conditions under which they make decisions. On February 15, 2010, the Committee for Prevention and Precaution was asked by the Minister of Ecology, Energy, Sustainable Development and the Sea and the State Secretary for Ecology to "develop a methodological analysis aimed at clarifying the issues and processes for public decision-making in situations of uncertainty, in particular when the decisions involve implementation of the precautionary principle".[1]

As an introduction to this analysis, it appears useful to clarify our approach and the principal concepts we will use.

Public decisions must often be made in situations of uncertainty, that is, situations whose development depends on unknown factors. **Uncertainty** signifies that the available knowledge does not allow a situation to be characterized as precisely as one would like; it is not a synonym for ignorance. The limits of existing knowledge must therefore be established as clearly as possible, to use it optimally.

The simplest representation of a situation of uncertainty is **risk**. We speak of risk when we are able to distinguish a set of potential outcomes for the situation, attribute degrees of likelihood to them, and estimate the scale of the consequences. In the field of environmental health, this means that a hazard has been identified and that the effects of its occurrence on society can be assessed. The measurement of risk must thus combine the probabilities of the occurrence of harm and its scale. The representation of risk by a single number, obtained by multiplying these two terms, is a frequent simplification but is not always appropriate.[2]

Risk assessment thus describes the scenarios for the occurrence and effects of a hazard and estimates their probabilities (whether quantitatively or qualitatively). When public decision-makers can rely on such assessments to develop measures for risk management, they are operating under a **prevention framework**.

In these cases, risk assessment is an essential guide for policy-makers. But it must not be considered on principle as a sufficient basis of information, for it is a synthesis that does not exhaust all the knowledge related to the uncertain situation. Accordingly, even in the context of the most common prevention issues, different risk estimates are acceptable, from a strictly scientific point of view.[3] This **margin of uncertainty** for risk assessment can be narrow and characterizable in the best of cases, but in many situations it is substantial and is itself therefore an important item of information for policy-makers.

In some extreme cases, it might even be impossible to represent uncertainty in the form of risk. That is the case, for instance, when it cannot be determined if a hazard exists at all or what the consequences of its occurrence would be.[4] This form of uncertainty is described as **ambiguity**.

---

* *key concepts of this report typed in bold on these two pages are defined in appendix 2.*

[1] See the complete text of the reference in appendix 1.

[2] In particular because such a quantification of the risk can lead to aggregating different forms of health, environmental or material damage without explicitly and clearly stating the modalities of this aggregation.

[3] Concerning, for example, how solid a building is in the case of a given seismic event.

[4] Some nanotechnologies put us in such a situation today (see sidebar 3 infra).

This description does not prejudge the seriousness of the feared damage; it characterizes a situation of uncertainty where the public decision-makers cannot rely on a risk assessment. It thus entails acting under a **precaution framework**.

The **precautionary principle** affirms that even in these cases, uncertainty is not a valid reason for postponing decisions to prevent potential harm.

It is normal that uncertainty is accompanied by differences in points of view, and sometimes disagreements and objections, especially when the community considers the measures to be taken. This is true in the presence of a risk and all the more so when there is a margin of uncertainty concerning its evaluation or ambiguity about its very existence. The choice of a formal representation and measurement of the uncertainty is not intended to eliminate these differences of opinion, but rather to provide them with an objective framework.

Public decision-making in an uncertain situation involves choosing whether or not to take public action to prevent or reduce potential harm and, if so, what action.[5] In practice, public decisions include several choices, generally made in stages: first, the applicable framework (none, prevention, or precaution), then the temporary action to be taken, and finally, the permanent action.

Public decisions are not made by any omniscient or omnipotent entity. They are based upon pieces of information about the situation, and take place in a social context where specific groups and individuals are involved. Even within the field of environmental health, public decisions have more dimensions than simply health and environmental impacts. They may have extensive human, social, and economic effects, and they have financial costs.

In democracies, informed decisions therefore presuppose repeated and ongoing dialogue with individuals and groups affected by the consequences and with holders of relevant information, especially in case of uncertainty. The fundamental argument put forward in this opinion is that these interactions must be systematically integrated into an established process for the development of public policy. This opinion proposes a formalization of this process.

Although its illustrations and examples come principally from the field of environmental health, this opinion concerns more generally the question of public decision-making in the presence of uncertain risks. Dealing with so vast and complex a subject, it cannot — and does not seek to — set forth or decree an exhaustive list of the inviolable principles of public action. In particular, it does not consider such fundamental aspects as the attribution of responsibility or liability, or the ethical questions related to uncertainty. Rather, relying on some practical examples and on recent developments in law, epidemiology, statistics, and economics, it attempts to clarify several concepts and to recommend several ways to improve public decision-making under uncertainty.

[5] In this opinion, the choices of taking no action or putting an end to a previous action will be therefore systematically considered as options available to public decision-makers.

Recommendations

The Committee for Prevention and Precaution proposes to establish clear principles and a detailed methodology for public decision-making in situations of uncertainty in our country. The Committee considers that such conditions will enable public authorities to distinguish, when necessary, those situations in which uncertainty can be characterized from those in which it cannot, and hence to place their action within a prevention or a precautionary framework.

The Committee accordingly makes the following recommendations.

1 PROCESS FOR PUBLIC DECISION-MAKING IN SITUATIONS OF UNCERTAINTY

- Set up a process for the preparation of public decisions, applicable to all situations of uncertainty with important stakes; designate and if necessary create permanent bodies where expert opinions can be obtained and debates held and that can be mobilized at specific stages of this process; delineate the procedures and methods to be followed at each stage.
- Launch the process every time a situation of uncertainty justifies it, and designate at the outset the person who will lead it; this person should conduct the procedures and coordinate the bodies involved in the process, and present the result of the process to the public authorities responsible for risk management.
- IIntegrate the stakeholders as such at specific moments of decision preparation and organize the succession of phases of consultation and phases of expert analysis.
- Organize, according to modalities to be established in advance, a post hoc assessment of the entire decision preparation process, to be conducted by a body that did not participate in it.

2 GENERAL PRINCIPLES

- Reaffirm the principle of separation of risk assessment and risk management, but also the concurrent need for dialogue between assessors and decision-makers.
- Evaluate uncertainty more systematically and take steps to explain and communicate uncertainty; for example, report confidence intervals with risk measurements whenever justified by the scale of the risk and the uncertainty concerning its assessment; increase researchers' and specialists' awareness of the need to discuss uncertainties in a scientific knowledge, related to specific disciplines and to an overall multidisciplinary approach.
- Promote interdisciplinary dialogue to develop a shared understanding of the problems of uncertainty, despite differences in terminology and concepts.
- Train specialists in the management of uncertainty.

3 SPECIFIC MEASURES

- Enhance scientific and legal investigations to define criteria of risk plausibility; better integrate epistemological thinking in the handling of this issue.
- In announcing a decision, include a complete presentation of its grounds (in particular the risk assessment, existing options, costs and benefits), the conditions under which it may be rescinded, and the period of applicability.
- Promote systematic and consistent assessment of the available risk management options; create or reinforce bodies responsible for this assessment.
- Organize a review of the proportionality of the precautionary measures to clarify the methods for comparison of potential harm and the cost of the necessary social and economic plans.
- In situations requiring precaution, adopt a flexible procedure that can be modified according to the changes in the situation and available knowledge.
- Assess the use of decision support instruments as tools for the collective construction of public decisions; develop economic research into risk and uncertainty.

CHAPTER I

Towards procedures for public decision-making under uncertainty

Section 1
Treat public decisions as the final result of a process for preparing and making decisions

Society frequently faces environmental or public health situations in which a doubt exists.[6] Organizations, social groups, and citizens express concern about the potential effects of exposure to different substances — such as nanoparticles today. Some health effects are blamed on possible causes, as when pesticide exposure is accused of reducing fertility. The efficacy of a preventive measure, such as a vaccine, is challenged. The questions can concern new or even future risks, but also long-standing risks, and may involve changes in the situation, in knowledge about it or in relevant expectations, as for air pollution today. Finally, these concerns may be either very minority opinions or the subject of a broad consensus.

To deal with these situations, public officials must be able to mobilize the available knowledge and information quickly, establish a dialogue among the social groups involved, and develop a response that is both informed and acceptable for society. Recent years have seen the creation of numerous official bodies and the emergence of technical and legal tools for this purpose. France has created agencies to provide expert advice and assessment for each of the major categories of risks. Stakeholders have organized to advance their own points of view and have been increasingly integrated into the debates. Risk-related concepts are broadly disseminated throughout a variety of statutes. The precautionary principle was included in the Environmental Charter and thereby became a constitutional principle in France. Its field of application has been progressively extended, especially in the area of public health.

Although some of these advances undeniably represent progress in dealing with risk, this progress is nonetheless insufficient, especially in situations of major uncertainty and controversy. On various occasions in recent years, health concerns have been addressed from a variety of standpoints, with a less than adequate effort to weight and link the elements of response. Too often, public officials have finally intervened only in situations of persistent or even heightened doubt. The conditions in which the precautionary principle should be implemented continue to be interpreted contradictorily[7] and are regularly contested in court.[8]

These difficulties highlight the absence of a frame of reference. In this context, it seems desirable today to take steps toward formalizing a process of preparation of public decisions – one that would integrate expert opinion, consultation, and debate in a more systematic fashion, taking into account

---

[6] The term doubt was deliberately not defined in the terminology discussion: it designates here any situation of concern by individuals or social groups relative to an uncertainty. The present opinion nonetheless does not deal with the problem of the initial handling of alerts, to which Corinne Lepage recently devoted a portion of her report, proposing especially:

"To handle external warnings, the High Authority for expertise (…) should be responsible for dealing with launching alerts, while obeying obligation of confidentiality. Without necessarily reaching a judgment on the substance, it should, following a well established procedure, validate the announcement of an alert, which does not imply validating the substance of the risk itself. Further examination is generally required before such validation. The degree of credibility of the alert, the reliability of the documentation, the good faith of the person transmitting the alert are the elements that allow the High Authority to reach a judgment." (Lepage Committee, Final report of 1st phase, proposal n° 21).

The doubt taken as a starting point in this opinion is situated between these two validations: we thus assume that an alert was judged credible, reliably documented in good faith, and we focus on handling the situation from that point onward.

[7] Invocation of the precautionary principle in favor of the vaccination campaign against the influenza H1N1 virus is a recent example. In the terminology of this opinion, the management of the risk in this case was governed by the rules of prevention, here, international rules. The different scenarios of pandemic development were known at the moment of its emergence, even though strong uncertainties, especially concerning the virulence of the virus and the vaccine scheme, did not allow a particular scenario to be favored. See also, on this subject, section IV.B.

[8] The courts themselves can interpret the principle in divergent ways. For example, the decision of the Versailles Court of Appeals on cell phone relay antennas contravenes on several points the requirements set forth by the Court of Justice of the European Communities for decisions under uncertainty. But these cases of divergence remain a minority (see section III.C.1).

the contributions and limitations of each. The implementation of such a process should be relevant to the specific character of each case: the issues involved, the degree of urgency, the extent of knowledge, the identity of the stakeholders, etc. A process tailored to each problem requiring a decision under uncertainty is thus necessary, but guidelines and a general architecture can nonetheless be recommended. This report makes such recommendations.

Figure 1 below summarizes the process we suggest. It distinguishes three types of phases: evaluation of the uncertainty, evaluation of measures, and the actual decision-making stages.

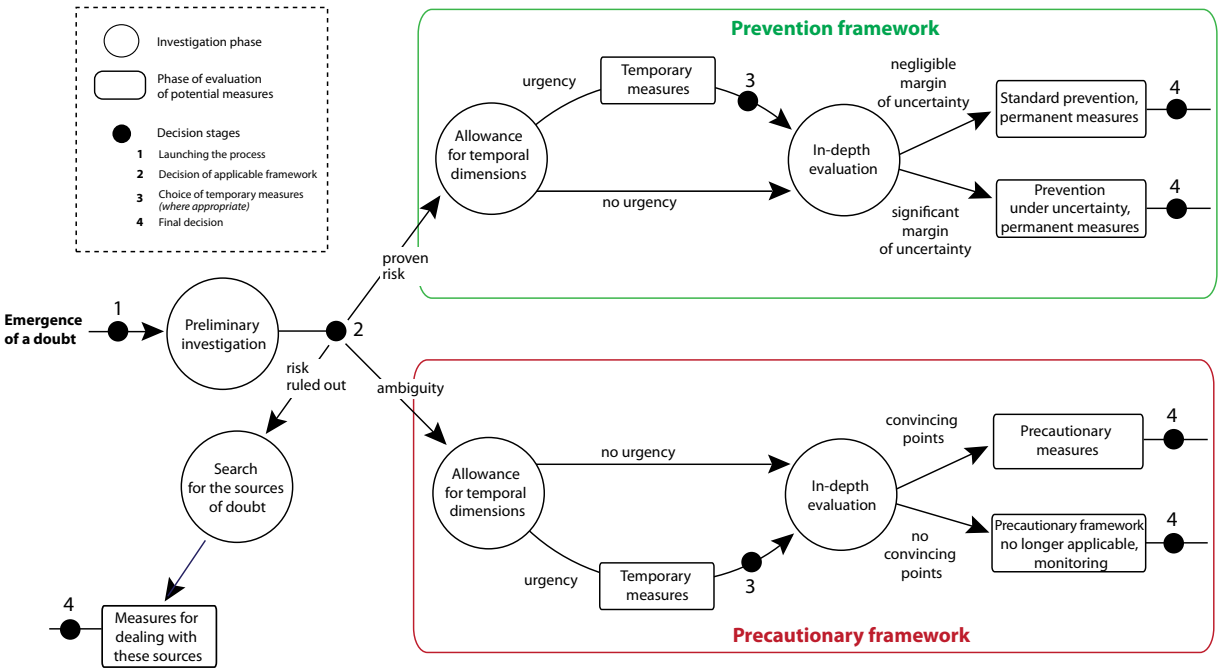


Figure 1. Simplified diagram of the preparation of public decisions

The following sections of this chapter address the questions of responsibility and of comprehensive assessment of the entire process. The rest of this report discusses the various elements of the process in detail. The second chapter deals with the initial stages (preliminary investigation, consideration of time-dependent factors, research and treatment of causes of doubt when risk is ruled out). The third chapter covers the assessment of uncertainty, and the fourth the assessment of the measures taken.

Section 2
Designate a process leader

Once an alert about a possible risk is considered credible, public officials should designate a person to direct and supervise the evaluation and consultation steps necessary before making a decision.

The first task of the leader will be to initiate the decision preparation process and to guarantee the smooth progress from the initial warning or alert to the choice of a permanent response by public decision-makers. The leader is not intended to replace the public officials or take on their responsibilities. At various points in the process ("decision-making stages" on the diagram), this person will present them with all the relevant information and evidence, take note of their decision, and continue with the task.

This process should thereby clarify and strengthen distinction between risk assessment and risk management.

This person should coordinate and where appropriate harmonize the various individual investigations taking place simultaneously before different bodies, especially within the government.

The designated leader should be empowered with the authority and resources necessary to conduct this task, which may involve a significant number of government departments. Ideally, the leader would come from an organization or agency outside the government (such as the National Commission for Public Debate or the Parliamentary Office of Scientific and Technological Choices) and should be granted, if warranted by the issues involved, the status of an interministerial delegate for the duration of the mission.

Section 3
Organize the assessment of the decision-making process

The decision-preparation process and therefore the mission assigned to its leader will be completed when long-term preventive or precautionary measures are implemented or the causes of doubt are dealt with by the decision-maker. A post-hoc evaluation process should be organized in advance, to ensure that lessons are learned from the practical experience acquired and to enrich the theoretical analysis. This evaluation should include the collection and review of any complaints by stakeholders, as well as an overall assessment of the process of integration of the expert opinions with the debate. It is not intended to assess the actual risk management decisions.

The task should be entrusted to a body that did not participate in the earlier process. It might, for example, come under the jurisdiction of the National Assembly Committee on Public Policy Assessment, created in 2009 and currently working on an assessment of the precautionary principle. The principles of the evaluation should be clearly stated and its methodology specified in advance, for example by a handbook of good practices. It would be advisable to follow the example of the post-disaster operational feedback assessments conducted today by the Inspection Services of various ministries.[9]

[9] See also, in this regard, the recommendations of the opinion issued by the CPP in 2008 on the subject of operational feedback after disasters.

CHAPTER II

Preliminary stages

Section 1
Mobilize experts and stakeholders from the outset

The first stages of the decision-preparation process require that an organization be set up with the participation of two distinct and complementary groups: stakeholders and scientific experts.

The stakeholders associated with the initial phase must be those most immediately concerned by the problem. The priority, at this stage, is to ensure that the principal points of view about the existence of a risk and the need for action are represented and that none of them mask any aspect of the situation. At a later stage, consideration of the advantages and disadvantages of different types of action will require the participation of a different and probably wider group of individuals affected by the health, environmental and socioeconomic issues involved.

The expert assessment, on the other hand, must simultaneously call on specialists of various disciplines (including epidemiology, toxicology, materials physics, and sociology), and on practitioners with different perspectives (researchers, engineers, managers, inspectors). In both groups it should also attempt to include persons with divergent points of view, if scientific or technical differences exist.[10]

It is obviously impossible to define in advance all of the disciplines or experts capable of shedding light on a given situation of uncertainty. The first expert advisory group established should therefore be empowered to enlist specialists covering other viewpoints likely to be useful. In all cases, the experts consulted should include not only specialists in the relevant biological, physical, chemical and ecological phenomena, but also social scientists in a position to identify the actors and social groups potentially affected by the risk and its management, and to analyze their representations and behavior, as well as the determinants of both.

The functioning of this committee must alternate between periods of dialogue among all of its members (stakeholders and experts) and others limited to the experts.

[10] On this subject, see the CPP opinion issued in December 2002 on expert assessment of the risks of industrial accidents.

Section 2
Initial issue: unfounded doubt, risk, or ambiguity?

Once a doubt is judged credible, the committee members must address two fundamental questions:

Is the doubt related to a proven risk or a case of ambiguity, or does the current state of knowledge justify ruling out any possibility of significant harm?

What actions must public officials take to deal with it?

The preliminary investigation phase is intended to develop a response to the first question. The response to the second question must then be considered under three different sets of rules: the prevention framework, if the risk is proven; the precautionary framework in case of ambiguity; and research into dealing with the sources of doubt, if the risk is ruled out.

The initial investigation must therefore determine whether:

- the doubt is unfounded, in the sense that the existing scientific knowledge and available data make it possible to exclude any risk;
- the doubt concerns a proven risk, which can therefore be assessed (or re-assessed) on the basis of existing scientific knowledge and available (or easily collectable) data;
- the doubt is characterized by ambiguity, that is, it is impossible to determine whether a risk exists or not on the basis of existing scientific knowledge and available (or easily collectable) data.

A decision that the doubt is unfounded does not mean that the societal concerns will simply be swept away by a ritual incantation of "scientific facts". Such concerns often result from ethical, cultural, social, or economic problems and require an appropriate response. In such cases, these associations must be clarified to help formulate a rational and fruitful debate. But these situations are not part of the field of uncertainty as defined in the introduction, and we will therefore not deal with them in further detail here.

The recent debate about the effects of cell phones and their relay antennas is an example of the consultation and analysis phase, and it led to the adoption of a rational and coherent precautionary approach. This debate demonstrated simultaneously the need for and the difficulty of a more systematic and better standardized organization of this type of procedure (see sidebar 1).

Sidebar 1 : Electromagnetic fields – Cell phone relay antennas

The recent debate around the potential hazards of electromagnetic fields emitted by the cell phone relay antennas illustrates the difficulties of public decision-making under uncertainty.

Human activity, with its applications of electricity and means of communication, produces many sources of electromagnetic fields, of much greater intensity than the fields in which human and animal populations learned to live across the millennia (terrestrial magnetic field, electromagnetic fields from solar activity or storms). We are now exposed to a fog of electromagnetic fields of different frequencies and with variable suspected health effects and physical properties: low frequency fields of 1 to 300 kHz, from electric power transmission lines, building wiring, and household transformers and appliances; intermediate frequency fields of 300 kHz to 300 MHz, associated with anti-theft devices in stores, video screens, radios, VHF television, etc.; radiofrequencies from 0.3.109 GHz to 1015 Hz including microwaves, UHF television, GSM and UMTS mobile telephones, microwave ovens, WiFi, DECT and WLAN wireless communication systems, radars, police and other emergency transmission networks, satellites, etc.; and finally ionizing radiation, from 1016 to 1022 Hz.

Extremely low frequency electromagnetic fields and radiofrequency electromagnetic waves have two components: an electric field and a magnetic field. The term "magnetic field" itself can refer to two different physical quantities, measured respectively in teslas and in amperes/meter. The electric field is measured in volts/meter. In the case of waves, electric and magnetic fields are interrelated, and it is sufficient to measure one or the other.

Despite the progress since the first cell phones, the power they generate that is absorbed by the brain exceeds by several orders of magnitude that due to exposure to a relay antenna. However, exposure is temporary and localized in certain parts of the body in the first case, while it is permanent and affects the whole body in the second. Generally, the two types are characterized by different physical units.

People living near antennas report a variety of symptoms, including headaches or insomnia. Double-blinded studies in hypersensitive volunteers have thus far not been able to establish the existence of a causal relation. Nonetheless, the reality of the symptoms, regardless of their cause, has led to the establishment of programs to manage them.

The differences in regulations between European countries (in levels and localization of the measurement) add to the confusion. For example, the limits on electric field values associated with electromagnetic waves for cell phone relay antennas range from 28 to 61 V/m in France according to the frequency, but are limited to 6 V/m in residential premises in Italy.

In fact, the levels measured in France are generally well below 6V/m, and reducing the limits would not necessarily have a direct impact on mean exposure levels. Application of a limitation to 0.6 V/m could, however, affect network coverage. One objective of the campaign of experimentation now underway is to verify the practical implications of lowering the regulatory limits.

Finally, the absence of convincing scientific information has not prevented courts from ordering an end to exposure in three lawsuits. More recently, neighbors complained of health problems due to three relay antennas that, according to the operator, were not yet in service.

In this situation, the decision to organize the widest possible consultation on this subject (at a "Grenelle" public forum on electromagnetic waves) and to report publicly that according to the scientific data the existence of a risk is more plausible for cell phones than for their relay antennas constitutes a positive step in a preliminary investigation. Without prejudging either the effectiveness or the proportional nature of the measures taken since then, these measures are consistent with the conclusion reached at the forum about the need for effective protection from cell phones, and monitoring and experiments for relay antennas. The precautionary procedure on which both measures are based is indeed a procedure of action. On the other hand, the forum does not appear to have fulfilled its ambitions in terms of the circulation and sharing of expert opinion, since it barely touched on questions such as exposure measurement.

This subject must now be followed up on a long-term basis, for only in that way can the hypothesis of health effects be permanently ruled out. Studies on the interaction of fields of different frequencies with biological tissue must be developed. Finally, an international consensus must be sought on emissions standards and their scientific basis.

In the latter two cases, those that interest us here, doubt cannot be excluded by science or available data. Society must cope with uncertainty — characterized either as a risk or as ambiguity. From this fork onward, public decision-making should follow the prevention framework in the first case and the precautionary framework in the second.

The preliminary investigation nonetheless postulates that before judgment the scientific validity of the evidence, all the points of view about potential risk must be expressed and taken into account. The preliminary investigation must therefore begin by an examination of the issue:

How should the question of the existence of a risk be formulated in this case?

At this stage, it is not yet time to seek a consensus. It is important to recognize that in situations of uncertainty, diverse opinions can be equally acceptable from a scientific point of view. At this stage it is also appropriate to analyze the ethical questions (for example, the information to be provided to the exposed population) and to define the scope of the liability raised by the uncertain situation. Finally, partners must be involved in the decision process, especially those who have knowledge to contribute, in particular about the limits of scientific representations and knowledge. Accordingly, a plurality of viewpoints is even more necessary for the adoption of a balanced position in these cases than for those where uncertainty does not play a major role.

Overall, the preliminary evaluation should include two or three phases: a period of consultation about the suspected hazards, the principal issues, the sources of uncertainty, the questions of values (such as solidarity or fairness in the distribution of risks) and finally the formulation of the question of whether a risk exists; a period of expert analysis of the available science and data on the question; followed if necessary by a final consultation about which classification is appropriate. However, the interaction between experts and stakeholders does not always allow an unequivocal determination of whether public action should be placed under a prevention or precautionary frameworks, as demonstrated by the hepatitis B vaccination affair (sidebar 2). The final choice belongs to the public officials.

Sidebar 2 : Prevention and precaution in the case of hepatitis B vaccination

The vaccination against hepatitis B provides an exemplary illustration of the overlap between the logic of prevention and that of precaution. For this reason, although it is not within the Committee's usual field of study (environmental health), the CPP chose to study it as part of this referral.

Like infection by other hepatitis viruses, hepatitis B virus (HBV) infection in humans can be symptomless and benign. There is also a risk of more serious forms. In the short term, after contamination, the major risk is that of fulminant hepatitis, which can require an emergency liver transplant. Later, there is a risk of development of particularly active cirrhosis and liver cancer (hepatocellular carcinoma).

Studies have proved that the vaccination against HBV infection is effective in preventing this disease. According to the summary of the characteristics of the product, studies have shown that the protection rate ranges from 95 to 100% in newborns, babies, children, and at-risk adults. A study in Taiwan also showed that the prevention of hepatitis B by this vaccination led to a reduction in the incidence of hepatocellular carcinoma in children aged 6 to 14 years.[11]

Vaccine tolerance is good. Side effects are described as very rare; they are benign and do not leave sequelae in the vast majority of cases.

Nonetheless, although a doubt still persists about the cause and effect relation, this vaccination may, very rarely, cause serious neurological diseases, such as multiple sclerosis. These possible associations must be confirmed, but the relation is plausible, and the pathological consequences, if confirmed, serious and irreversible.

Based on these results alone, the benefit/risk ratio of vaccination is incontestably high. That is, the incidence of neurological disease induced by this vaccination, if this risk does exist, is infinitely smaller than the risk of developing severe liver disease in the absence of vaccination. This is especially true for populations at risk because of insalubrious environmental conditions, immune compromise, or their occupation.

Moving from statistical reality for the population as a whole to individual decisions about vaccination nonetheless raises three types of problems. First, each vaccination has a higher benefit for society as a whole than for the individual alone, because it reduces the general risk of infection. It is this gap between the social and individual benefits that justifies vaccination campaigns by public officials, incentive measures, and even in some cases the decision to make

[11] Dictionnaire Vidal, 2009 edition

vaccination mandatory. Secondly, however, a centralized determination of a "proper" or "correct" attitude towards risk raises the question of each individual's free will and capacity for self-determination. There is, finally, the question of information: although the public official responsible is supposed to have better knowledge of the scientific data concerning the risk, individuals may certainly have better knowledge of their personal exposure to the hazard. Every public health decision, especially those related to vaccination, presupposes a balance between these aspects. In the case of the hepatitis B vaccination, this is complicated by the fact that the data related to the potential risk induced are not conclusive.

In such cases, the best solution seems to be an intermediate pathway that seeks to limit the disadvantages of generalized vaccination and of purely individual decisions. The decision must therefore be made on a case-by-case basis by the patient or the person responsible for the patient (parent or guardian), as part of a process of informed consent, together with the caregiver, in this case the physician, who is (or should be) trained for this particular conversation.

Section 3
Consideration of the time frame

Once either prevention or precaution has come into play, the public decision-preparation process must examine the temporal dimensions of the issue. Various phenomena may modify the uncertainty and the options available for dealing with it. For example, a substance may be disseminated in the environment and cause irreversible ecological or health effects, with no possible subsequent reparation. Conversely, scientific or technical developments can open up new possibilities of risk control. These dynamic aspects must be taken into account at an early stage of the analysis.

This is particularly so when the preliminary investigation reveals an emergency. For a phenomenon that is either developing rapidly or has irreversible effects, temporary measures may be required immediately, to be refined later, after a more rigorous and complete evaluation. It necessarily follows that the content of measures must change between the short- and long-term responses and that the nature of the evidence on which they are based and the procedures for their implementation must also evolve. It is important to present temporary measures from the beginning as such and to specify the conditions that will suspend or end them (in the case of either a transition to permanent measures or the end of the emergency).

In practice, a divergence is frequently observed between the dynamics of the risk and the decision-making process. The case of nanoparticles is an example. In this field, the government sponsored both a major research effort and a vast public debate. In the context of the Grenelle Environment Forum, it proposed to identify the products containing nanoparticles and make their labeling mandatory. Some major producers have taken protective measures in accordance with the legislation on carcinogenic, mutagenic and reprotoxic (CMR) substances, as the CPP recommended in 2006.[12] Nonetheless, despite scientific information attesting to the existence of an ambiguity, if not a proven risk (see sidebar 3) and although the production and use of nanoparticles is expanding rapidly, no regulations have yet been enacted to protect workers, no preliminary evaluation preceded their marketing either in France or in the European Union, and problems of traceability and the definition of possible liability have not yet been dealt with.

Finally, in order to take temporal dynamics into account, the delay in implementing measures must be taken into account, hence the need for examining individual and social behavior. Some measures can be put into effect rapidly and will be accepted easily; others will require significant technical preparation and material investments; still others will involve the implementation of burdensome organizational or major behavioral changes, and will require a period of preparation, training, and support or guidance. In some cases, the exposure of people or environments during a long phase of investigation and development of suitable conservatory measures may also present real dangers, which must be considered.

[12] See the CPP opinion in 2006 on the subject of the hazards and risks related to nanotechnologies and nanoparticles.

Sidebar 3 : Summary of scientific results about the hazards associated with nanoparticles

Studies by physicists and chemists have shown that solid particles acquire new physicochemical properties when one of their dimensions is less than 100 nanometers (nanometric particles or nanoparticles). The potential applications of these properties spurred the development of nanotechnologies. Unfortunately these same properties cause them to induce biological reactions significantly greater than particles of similar chemical composition but of larger size (micrometric particles):

- increased fraction deposited in the respiratory system;

- easier progression across tissue barriers (epidermis, alveolar-capillary barrier, intestinal mucus, blood-brain barrier, placental barrier);

- increased proinflammatory cellular response (epithelial cells and macrophages);

- increased cytotoxic and genotoxic response.

Moreover, it has now been demonstrated that at equal nanometric dimensions, nanoparticles of similar chemical composition have higher cellular and tissular toxicity when:

- the specific surface area (exchange surface area per unit mass) is larger;

- the surface reactivity is greater (in its native state or after functionalization of the surfaces);

- the particles are longer (nanotubes, nanothreads);

- the particles are more insoluble (biopersistence).

The available data on the potential effects of nanoparticles are based above all on experimental models, either in vitro (cell cultures, the representativeness for humans of which is often questionable, especially cultures of transformed lines or cells of animal origin) or in vivo (especially interesting when they reproduce the physiological penetration route, such as inhalation, ingestion, or percutaneous application).

The nanoparticles tested come from:

- engineered nanoparticles, from nanotechnologies (their physicochemical characteristics are defined by the manufacturing process, but our knowledge of the kinetics of their aggregation and disaggregation in air and in biological media is incomplete),

- or the ultrafine aerosol fraction (ultrafine particles) in atmospheric pollution phenomena (particles of diverse granulometry and very complex composition, which vary according to the emission source and are always associated with other particulate and gaseous components).

Nonetheless these studies are remarkable for the reproducibility of the effects observed. In most cases they demonstrate a dose-effect relation. The best established effects concern the inflammatory response of the respiratory system. The most troubling effects involve cardiovascular response and genotoxic effects. The effects whose consequences remain to be demonstrated concern transplacental passage and migration of particles in the central nervous system (via the blood-brain barrier or the olfactory nerve).

CHAPTER III

Evaluating uncertainty

Section 1
A consistently repeated necessity

As stated in the introduction, uncertainty is a general concept, and risk is its simplest formalization. A common form of uncertainty evaluation is therefore risk evaluation, an activity that follows well-established scientific protocols, mobilizes substantial expert and research resources, and is the foundation for risk management decisions in the principal domains for which health effects are feared, such as environmental health, natural disasters, industrial accidents, and food safety. Risk assessment is now being applied in other fields of public decision-making, including environmental protection and economic regulation.[13]

Further improvements in the theory and practice of risk assessment are desirable, especially when it comes to the integration of stakeholders. The CPP has issued several opinions on this topic in recent years.[14] The present opinion, however, deals with the need to go beyond these evaluations in the formal consideration of uncertainty. This need is due to the fact that risk is a synthesis, expressed in a predetermined form (a feared event, consequences, or a probability distribution). This synthesis, however, does not exhaust all the information available about an uncertain situation.

In prevention situations, where risk can be assessed, it necessarily leaves aside some of the uncertainty. A risk assessment necessarily requires choosing representations and characterizations among a larger set of possibilities.

Consideration of the uncertainty on the result of a risk assessment is a long-standing demand, stated repeatedly since the procedure became official. It was expressed in 1983 when the US Academy of Sciences formalized the risk assessment process for environmental health.[15] It still is, a quarter of a century later, as the same Academy once again takes up questions about these assessments.[16]

This need is even greater when a comprehensive risk assessment is impossible, that is, when knowledge is insufficient to establish its existence scientifically. Public decision-makers then find themselves in a situation calling for the application of precaution.

In similar situations in the past, decision-makers considered that the justification of their decision did not require them to produce an objective assessment of the uncertainty, especially when they could not do so. These decisions were thus subject to contestation, and a good number of them ended up in court. Judges in various jurisdictions have generally reaffirmed the need for public decisions to be based on a formal consideration of the uncertainty involved.

Analysis of the means for taking uncertainty into account remains incomplete, and legal decisions alone cannot make up for the absence of the necessary theoretical framework. They nonetheless spur public authorities to act accordingly.

The process of decision preparation must therefore include a stage to evaluate uncertainty, under both prevention and precautionary frameworks. The sections that follow include some proposals for this purpose, and identify the subjects for which deeper methodological analysis is required.

---

[13] See, for example, the European Commission communication on the subject of its strategy for "Better regulation in the EU" (COM(2009)15).

[14] See, for example, the CPP opinion in 2002 on the expert assessment of the risks of industrial accidents.

[15] National Research Council (1983), *Risk Assessment in the Federal Government: Managing the Process*, NAS-NRC committee on the institutional means for assessment of the risk to public health. National Academy Press, Washington DC.

[16] National Research Council (2009), *Science and Decision, Advancing Risk Assessment*, NAS-NRC committee on improving risk analysis approaches used by the EPA. National Academy Press, Washington DC.

Section 2
Measuring the margin of uncertainty within a prevention framework

1. What is a risk assessment procedure?

Risk assessment is a scientific process intended to assess the degree of probability, the extent and the severity of the effects of an event that is feared. It is based on a representation of the causal chain from the initial phenomenon (e.g., strong precipitation, dissemination of a toxic substance into the environment, power outage at a nuclear power plant) through the final effects (e.g., health or environmental impact or economic cost). Its methodology varies from one domain to another. In the environmental health field, for example, it is usually performed in four stages: hazard identification, estimate of the dose-response relation, exposure assessment, and risk characterization. Frequently, its results are expressed as probabilities, of both consequences and of the mathematical expectation of damages. Nonetheless, the assessment need not necessarily be quantified; it can be based on qualitative data.

Risk assessment is related to the state of knowledge at a given time. It also has a cost and is therefore calibrated as a function of the stakes. One of the purposes of the preliminary investigation mentioned in the preceding section is to provide the information for this calibration.

When a risk is anticipated (for example, before approval of a new pesticide identified as a hazard source), an initial *a priori* assessment must be conducted, based on results obtained in conditions different from reality (laboratory tests or simulations).

When seeking to estimate an existing risk (for example, radon exposure in homes), the assessment is performed *a posteriori*, and the site data are considered.

In all cases, the assessment must be updated regularly to take advances in knowledge and changes in the situation into account. The data used to estimate risk for an *a priori* assessment must be compared with real-life conditions. For example, the assessment of risks associated with hormone administration to livestock must consider the possibility that the farmers will not follow good practices in hormone administration as well as the difficulties in organizing the monitoring of actual practices. If these observations are made after the product is approved and available, they may lead to a new *a posteriori* assessment. Sidebar 4 offers an illustration of the parallel development of risk assessments and site observations in a case of prevention that has thus far been successful, that of exposure to lead in automobile fuel.

Sidebar 4 : Risks associated with lead exposure

Clinical lead poisoning, especially due to occupational exposure, has become rare because of legislatively-mandated improvements in industrial hygiene. The public health problem today concerns instead the effects that can occur at low doses. The most troubling effects are those on the central nervous system and psychomotor development in children. In 2004, the International Agency for Research on Cancer concluded that inorganic lead is a probable carcinogen for humans (Group 2A).

Beginning at the end of the 1960s, regulations of emissions of industrial pollutants, as well as the 1976 statute on classified installations for environmental protection, reduced lead levels in air pollution. More recently this reduction was accompanied by a reduction in emissions from automobiles, due to a regulation (based on the 1982 European directive). Lead in automobile fuel was the major cause of exposure in urban areas. Its progressive elimination led to a rapid reduction in blood lead levels: depending on the country and the age group considered, within a decade of the implementation of this ban, blood lead levels fell by 40 to 70%.

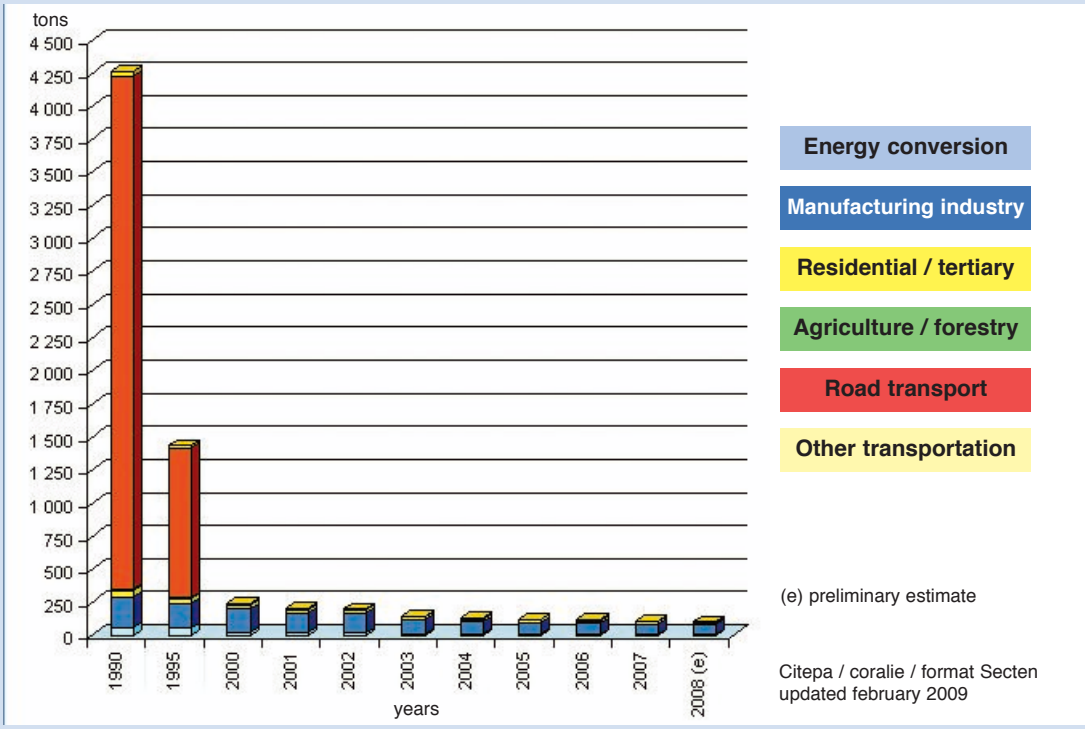


Figure 2 : Atmospheric lead emissions by industry in metropolitan France, 1990-2008

This important public health success nonetheless remains incomplete. Recent epidemiologic data indicate that the dose-response relation of children's cognitive and psychomotor development has no threshold of action. Lead exposure must therefore be reduced as much as possible, including by reducing other reservoirs of lead exposure. Lead paint has not been totally eliminated from homes built before 1950, and water pipes made of lead still exist in many cities, representing a source of exposure, especially for children. Those who live in old buildings still have a very high risk of childhood lead poisoning.

2. Allowing for uncertainty in a risk assessment

A risk assessment is supposed to identify and describe all relevant causal relations, from the initial phenomenon to its final effects. This involves many uncertainties. Scientists may suspect the influence of a factor even if it has not been clearly demonstrated (identification uncertainty), hesitate between alternative representations of a causal relation (model uncertainty), not know the exact numeric value involved in a relation (parameter uncertainty). These different types of uncertainty, which can affect each stage of the risk assessment, must be treated differently.

Parameter uncertainty is usually determined by statistical methods covered by a substantial scientific literature.

The standard treatment for uncertainty on the results of modeling is to use conservative hypotheses (to maximize the risk). In toxicology, for example, "uncertainty factors" are used to transpose to humans the results from animal models; they are applied to the estimate of the "no observed adverse affect level (NOAEL)" dose. For example, the dose corresponding to a toxicity threshold observed in animals is conventionally divided by a factor of 10 before being transposed to humans, to protect against the possibility that our species is more sensitive to the toxic effects considered. The uncertainty in these cases is not evaluated, but it is bounded (at least, so we hope). These methods are commonly used for exposure estimates and characterization of dose-effect relations.

Uncertainty about the structure of the model itself is more difficult to assess, because the complete set of possible models is generally difficult to define. The techniques of model verification theoretically make it possible to find acceptable models within a set of limited size, but this uncertainty is rarely estimated rigorously.

Examining the overall risk assessment procedure shows that the different forms of uncertainty can both interfere with and reinforce each other (see sidebar 5). Overall uncertainty can then be estimated by propagation techniques for example, by randomly choosing the value of each characteristic within a range of possible values, calculating the risk for this "set" of values, repeating the operation again and again (generally thousands of times), and finally collecting all the risk values thus estimated. The method is known as Monte Carlo sampling for its resemblance to watching a roulette table in a casino. These quantitative forms of uncertainty analysis can usefully be combined with global sensitivity analysis.[17]

Sidebar 5 : Propagation of uncertainty in a complex model

An epidemiologic study identified an excess of leukemia in youth aged 0-24 years between 1978 and 1996 in the canton of La Hague, in France. In response to the questions it raised, a joint study by a group of partner institutions estimated the number of cases that risk assessment models could attribute to releases from the nuclear fuel reprocessing plant there. After two years of work, the group reported its results in 2000.[18] Because the number of attributable cases was near zero (0.0014), it was decided to conduct an analysis of the uncertainty about this figure.

It quickly became apparent that the assessment had to be simplified, given the large number of probability distributions to be estimated and models to be implemented. Of all the models in the risk assessment chain, only the environmental transfer models were analyzed. In particular, the models calculating exposures during incidents at the site and those used to estimate either in utero exposure or the dose-effect relation were left out of the study's scope. In short, among thousand of indicators, only the 200 most important, chosen from sensitivity studies, were selected for the uncertainty evaluation. Distributions for these indicators were estimated under a simplifying hypothesis that the indicators were statistically independent. Despite all these simplifications, the work took several teams more than a year.

[17] Saltelli A., Ratto M., Andres T., Campolongo F., Cariboni J., Gatelli D., Saisana M., and S. Tarantola (2008), *Global Sensitivity Analysis*. The Primer, John Wiley & Sons.

[18] Rommens C. et al. (2000), 'Methodology and results of the Nord-Cotentin radioecological study', *J. Radiol. Prot.*, 20, 361-380.

It was accordingly possible to describe the uncertainty around the number of cases expected after the transfer of radioactivity into the environment. The reference risk initially calculated without an uncertainty analysis was 0.0009 expected cases. The figure in this sidebar superimpose over this value the distribution calculated by the uncertainty analysis. The result is typical. There is approximately a 5% chance that the number of expected cases is less than 0.001, and a 5% chance that it is greater than 0.0024. This relatively low uncertainty did not call the initial assessment into question. Note that the initial value of 0.0009 cases, which resulted from the "most plausible estimate" of each parameter value by the experts, finally turned out to be implausible. It is frequent, especially in complex cases, for an uncertainty analysis to show that the construction by experts of the "plausible" values is in fact biased. Our intuition of the mean may be misleading, and uncertainty analyses then have the merit of correcting it.

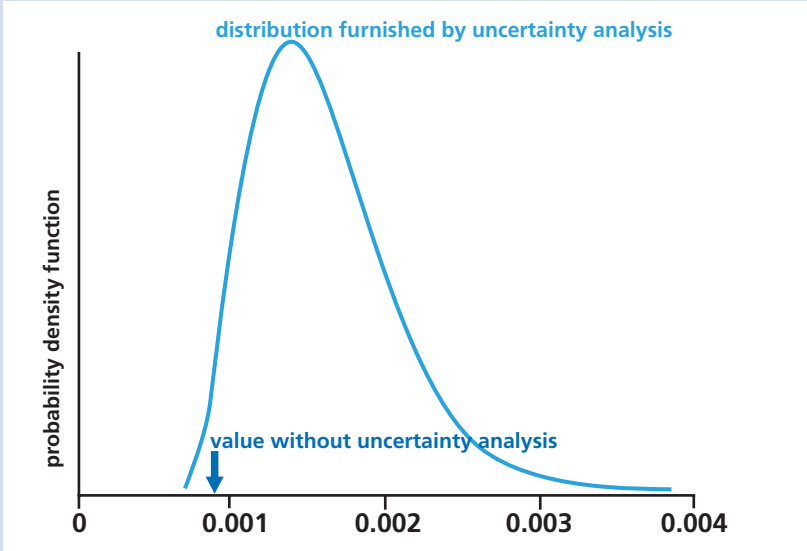


Figure 3 **: Distribution of the number of cases of leukemia expected in the population of the canton of La Hague following environmental transfers**

Access to methods and tools for calculating uncertainty in risk assessments is difficult for economic and logistic reasons. They are nonetheless extremely useful for policy-makers, who can thus determine what risk scenarios must be considered and which scenarios, although possible, can be considered too hypothetical. Because these methods are useful for determining confidence intervals and the probabilities of exceeding them, they can be integrated into standard decision-making processes.

In the particular case of hazard identification, recourse to qualitative treatment of the uncertainty is frequent. Groups of experts compile, assess, and weight the "elements of proof" of a hazard, thereby classifying its plausibility. One example is the classification of carcinogenic agents by experts at the International Agency for Research on Cancer, the European Union, or the US Environment Protection Agency, based on toxicological and epidemiologic studies that are nonetheless derived from quantitative and statistical procedures (see sidebar 6). The procedure of assessing and weighting hazards by expert groups is necessary in particular when we lack human data from epidemiological studies. Integration of a causal factor of uncertain influence is frequently abandoned, for example. The history of bridge engineering shows that failures are rarely attributable to an insufficient safety factor for the vertical load. Instead they are most often associated with the failure to consider forces such as wind or frost.[19]

[19] Petroski, H. (1994), *Design paradigms: Case histories of error and judgement in engineering.* Cambridge University Press, Cambridge.

Sidebar 6 : Uncertainty on the existence of a hazard

The International Agency for Research on Cancer (IARC), a part of the World Health Organization, classifies substances into five categories according to their "degree of carcinogenic risk for humans" (Table 1).

More than a classification in terms of risk, it is actually a qualitative assessment of the uncertainty on the carcinogenic hazard of various agents. Group 1 thus contains the substances for which IARC considers sufficient proof exists of their hazardous nature; the uncertainty in this case is considered negligible. Group 4, on the other hand, contains substances for which harmlessness has been verified in sufficiently general conditions to estimate it as probable, which can also be interpreted as low uncertainty. It should be emphasized that the hypothesis of the total absence of hazard is by nature impossible to validate and that, even defined less categorically, group 4 contains only one substance. Groups 2A, 2B, and 3 correspond to increasing degrees of uncertainty.

IARC began these evaluations in the mid-1960s. Table 1 shows that fewer than a thousand potentially carcinogenic environmental factors (chemicals, complex mixtures, occupational exposures, physical and biological agents, and lifestyle factors) have been examined since then, because of the considerable time and money required for a thorough examination of a single agent or situation. The number of potential carcinogens that could or should be examined is immense. It is estimated that 100 000 chemical agents or mixtures are sold in the developed countries, a substantial share of which would warrant examination. This number does not take into account the enormous number of molecules whose natural origin does not necessarily imply that they are free of carcinogenic potential.

Expert groups judge these agents and classify them; the judgment is thus partially subjective. Accordingly, the different bodies conducting this type of evaluation (including, in addition to IARC, the US Environmental Protection Agency, the European Union, AFSSET, etc.) can classify the same agent differently, even though they rely on the same data. We note in this regard that the European classification, which has a direct regulatory impact, has the flaw of not clearly separating expert opinions from management decisions.

Table 1 **- Classification of carcinogens by IARC in 2007**

Category	Classification	Number
1	Carcinogenic to humans	108
2A	Probably carcinogenic to humans	64
2B	Possibly carcinogenic to humans	240
3	Unclassifiable as to carcinogenicity in humans	487
4	Probably not carcinogenic to humans	1

Qualitative approaches to uncertainty and the classification of carcinogenic agents have similar advantages. For example, the Grenelle Environment Forum finally considered carcinogenic, mutagenic and reprotoxic agents in categories 1 and 2, but not category 3. That is, the expert advisory group used the classification established by European Union, and chose not to select for regulation the category of "substances and preparations of concern for humans because of their possible CMR effects but for which there is not enough information available for a satisfactory evaluation". The decision thus determined a level of plausibility, defined qualitatively, from which risk should be evaluated according to the standard methodology for prevention. Below that level, any risk should be considered according to other modalities.

Section 3
Evaluating ambiguity within a precautionary framework

1. Legal requirements

Analysis of the jurisprudence shows the controversial nature of decisions under the precautionary model and demonstrates the difficulties that this type of uncertainty presents to public decision-makers. At the same time, it allows us to identify the cause of most litigation: the absence of a scientific foundation recognized as objective.

Almost all the courts that have decided this question, from the World Trade Organization (WTO), to the Court of Justice of the European Communities (CJEC) and national judicial systems, have reached the same conclusion. This relative—but notable and increasing — homogeneity is especially remarkable for the WTO. The precautionary principle, although expressed affirmed by legislation in some of these jurisdictions (national courts, CJEC), is not part of the law of the WTO.

The jurisprudence relative to the precautionary principle tends to assume that risks can always be assessed, albeit sometimes only partially; that it is possible to take provisional measures based on such an evaluation, while awaiting more thorough scientific data; and that research must be conducted to obtain the additional data.

Courts have tended to impose two types of requirements. One deals with the method, the other with the substance.

The methodological requirement holds that decisions under uncertainty are possible on condition that the decision is backed by a scientific approach or, more precisely, by a risk assessment. This requirement involves relativizing the role attributed to this evaluation in the justification of the measures. Science must not be allowed to mask the uncertain nature of a situation by the application of excessive hypotheses. Risk assessment alone cannot determine risk management decisions in the standard prevention model, and still less in a context of strong uncertainty. Although it cannot dictate the decision, the risk assessment is nonetheless a prerequisite that has become an essential requirement in litigation on precaution.

From a substantive point of view, even a partial risk assessment must be supported by sufficient scientific data to be considered serious evidence. It cannot be based only on hypotheses. At that point, the risk must be "sufficiently documented" by solid and specific scientific indications. Although they cannot totally remove the uncertainties, they establish that its existence is not improbable; the measure must be "sufficiently supported" by scientific data; "serious and conclusive indications" are demanded, evidence that reasonably leads to the conclusion that the implementation of the precautionary principle is necessary".[20]

Jurisprudential imposition of these two requirements essentially reserves recourse to precaution for risks that are considered plausible. But what level of plausibility can be considered sufficient? In the absence of a complete evaluation, precisely what quantity of data should persuade decision-makers that the risk justifies the adoption of precautionary measures? Jurisprudence has begun answering some of these questions. Courts and tribunals have considered especially that the risk assessment must be specific, that it must present current scientific theses transparently and objectively (that is, both sides of the argument), and that it must be based on scientific opinions themselves founded on principles of excellence, independence and transparency.

[20] Noiville, Ch. (2009), "Science in Precautionary Measures. A Synthesis of ECJ and WTO Case Law", Co-Extra report, forthcoming in E. Truilhé-Marengo, *Expertise judiciaire en matière sanitaire et environnementale*, 2010.

2. Towards criteria of risk plausibility

To justify a decision under uncertainty, a risk assessment must explicitly cover the specific case that is the subject of dispute, while being based on general principles. Specificity is required for the suspected hazard, the conditions (geographic, temporal, etc.) in which it might occur, and its possible consequences. Failure to meet this criterion is the most frequent stumbling block for precautionary measures declared illegal by courts.

In French law, the Council of State has held that "an impact study (that) generally mentions the risks of dissemination of pathogenic microorganisms (...) but presents no specific analysis of these risks"[21] does not meet the requirement of precision. On the other hand, an evaluation that takes into account the specificities of the municipality in which a GMO will be planted (size of plots, absence of nearby conventional agriculture, basin protected from the wind) would be sufficiently precise.[22]

In European Community law, the requirement for an assessment that is detailed, case-by-case, and specifically considers the feared risk is applied quite strictly.[23] For example, the assessment of a completed development will not be considered equivalent to the assessment of a plan or a project underway, even if references to some items are permissible.[24] Similarly, an opinion mentioning that vitamin-enriched food exposes the population to levels exceeding the safety limits cannot prevail if it only mentions this general risk without specifying "the vitamin concerned, the extent to which the limits would be exceeded, or the risks that this excess would involve".[25] Thus, in the same vein, a study on vitamin and nutrient intake by the Dutch population cannot substitute for a precise analysis of the six vitamins regulated by the Netherlands (because) even though it may be useful as a complement to the assessment, it does not indicate the specific dietary habits of the Dutch nor the extent and severity of the potential risks".[26]

This demand for a thorough and specific assessment of the feared risk is verified even more strictly when the risk is used to support a national measure that overrides European Community law.[27] To justify such a measure, the State concerned must demonstrate that its evaluation shows a specifically national risk, related to particularities of the country or region (e.g., dietary habits, or particular or exceptional ecosystem).[28]

The WTO applies similar requirements of precision and adaptation to the particular case, stating that the evaluation must be appropriate to the circumstances. The cases about hormones and biotechnological products are typical from that point of view (see sidebar 7).

---

21 CAA Nantes, 21 June 2005, n0 04NT00315, SA Favé.

22 EC, 9 February 2007, Minister of Agriculture and Fishing v. Confédération paysanne du Gers.

23 Conclusions of the Attorney General M. Poiares Maduro, 14 September 2004, C-41/02. See also EC Commission v. Netherlands, point 44.

24 C 418/04, Commission / Ireland, 13 December 2007, point 246.

25 C-24/00, EC Commission v. Republic of France, 5 February 2004, points 53, 61 and 62.

26 Conclusions of the Attorney-General Poiares Maduro, 14 September 2004, C-41/02 49. EC Commission v. Netherlands, points 48 et seq. ; C-236/01, Monsanto.

27 C-439/05 P and C 454/05 P, Land Oberösterreich and Austria v. EC Commission, 13 September 2007, point 65.

28 See the Commission's decision to nullify the decision of the Land Oberösterreich to ban GMOs, preambles 63-68, 72, 73 and, on this decision, the combined cases C 439/05 P and C 454/05 P, 13 September 2007, Land Oberösterreich and Austria v. EC Commission, cited above. a problem specific to the Member State.

Sidebar 7 : Decisions of the World Trade Organization panels in disputes involving biotech products and hormones

In the biotech products dispute, the WTO panel determined that the arguments offered by the EC to support the disputed measures sometimes seemed to object to the method followed ("evaluations of risk assessment procedures"), which does not replace an assessment of the negative effects of GMOs. In other cases, according to the panel, the EC brief simply stated the difficulty of assessing the potential risks of these products, thereby begging the question, and accordingly recommended that their use be avoided in the current state of scientific debate ("incidence of the transfer of antibiotic resistance from marker genes used in the production of some biotech plants to bacteria in the human gut cannot be fully evaluated"; "the results about the consumption and growth rate of larva have potentially profound implications for the preservation of monarch butterflies"; "the large land area covered by corn in this region suggests that a substantial portion of (monarch butterflies) may be within range of corn pollen.").[29]

The panel in the hormones case similarly determined that the EC assessment was insufficient. In that dispute, the EC relied on a series of studies from which it deduced that the hormone residues present in beef fattened for anabolic purposes were dangerous for human health (paragraph 197 et seq.).[30]

These data did not, however, rationally support the EC measures. The minority scientific opinion had been reported at a conference and was not strictly speaking the result of scientific work. The scientific proof in the IARC monograph and the articles dealt with the carcinogenic potential of whole categories of hormones or of hormones generally. These were therefore general studies about the carcinogenic potential of hormones and not specific studies on the effects of hormones used as anabolic steroids in meat and meat products intended as food.

Discussing the evaluation of the new synthetic hormone, melengestrol acetate (MGA), the EC referred to an IARC monograph that covered progestins generally. Because the EC considered MGA to be an anabolic agent mimicking progesterone action, it considered the monograph particularly useful for reflection. The panel and then the appellate body, disagreed with this perspective: in their eyes, there was no evidence that MGA was chemically or pharmacologically similar to progestins or what effects it had on consumers as residues in meat. In reality, no scientific study and no international guidelines have approached MGA from such an angle. In these conditions, the IARC monograph could not be considered an admissible risk assessment (paragraph 201).

Finally, the CE put forth problems of detection and monitoring associated with the failure to follow good veterinary practices (and likely to result in excessive hormone levels in meat). The panel and then the Appellate Body held that no scientific study allowed a prejudgment, that the concerns of the EC were based only on theoretical possibilities, that it was required to demonstrate facts, especially since there were no reasons why monitoring of hormones should be more complicated than monitoring veterinary drugs, the use of which is authorized in Europe.

In sum, all the EC's arguments, while useful and relevant, were insufficient ("relevant but not sufficient") because, among other things, they were not specific to the feared risk.

[29] GS, Biotech Products., par. 7.3077, 7.3079 and 7.3097.

[30] A 1982 report from the work of 3 European scientific committees; proceedings of a symposium of World Animal Health Organization in 1983 on the use of anabolic steroids in livestock production; a 1987 monograph of the International Agency for Research on Cancer; the 1988 and 1989 reports of the mixed FAO/WHO Committee of experts on food additives; a 1995 conference organized by the EC on the topic, "Growth promotion in meat production"; a series of scientific articles; a minority scientific opinion.

Next, the evaluation must take into account all the available data. The evaluation must certainly have a local foundation, because it must concern the specific risk that is feared. Nonetheless, it must not be limited to the results of national research but be open to all the findings available internationally.

When the data are controversial, as is often the case under uncertainty, the assessment must include a comparison of the various scientific theories under consideration. That is, to be objective (stating the arguments on both sides) and transparent, the evaluation must be founded on a comparison of the most representative scientific theories and the scientific positions advanced by the different protagonists. Better, it must take into account all the opinions, dominant, minority and marginal, as long as they result from a scientific study, in the strict sense of the term.

The quality of the evaluation depends on the quality of the experts who conduct it; it does not suffice that that scientific opinions collected by the officials have a "scientific or technical character" and were issued under regular conditions. Scientific opinions must be based on the principles of excellence, independence and transparency (CJEC) and come from "qualified and respected sources" (WTO). There is now a sort of consensus on this point: the Constitutional Council confirmed similar guidelines for scientific experts in France, when it approved Act n. 2008-595, dated 25 June 2008, concerning GMOs.

Note that some vagueness remains when these general principles are transformed into operational rules: is any marginal opinion admissible? Must scientific quality criteria be specified, such as the format of publications? What can be done to avoid defining the state of scientific knowledge as equivalent to the dominant opinion within the scientific community? The past, after all, is rich in illustrations of the risk of such an assimilation.[31]

It might be useful to compare these questions to those in disciplines such as toxicology, epidemiology, or climatology, where the plausibility of risk is also a problem.

3. Causal uncertainty as the source of ambiguity

Ambiguity most often arises for risk scenarios in which an element of the causal chain, running from the hazard to the final effects, is uncertain, in the sense that the causal relation on which the element is based can neither be established nor rejected. The question of the plausibility of the risk can then be reformulated as the question of the plausibility of the causal association.

Past examples are plentiful. Placing them in historical context, especially in terms of scientific knowledge makes it possible to follow developments in the nature of uncertainties.

When worries about mad cow disease first arose at the beginning of the 1990s, the very possibility that bovine spongiform encephalopathy could be transmitted to humans as variant Creutzfeldt-Jakob disease was challenged. The uncertainty then was in the domain of ambiguity and only progressively moved into that of risk as discussion came to include concepts such as the minimal infective dose (although the risk estimates remained strongly divergent).[32]

In 1974, Molina and Rowland used recent findings about the chemistry of the stratosphere to show that ozone could be destroyed by chlorofluorocarbons (CFCs).[33] Because of the potentially catastrophic consequences on humans and the biosphere, the United States banned CFCs in aerosol containers in 1978, and the European Economic Community (EEC) in 1980. In 1985, two months before the discovery of the ozone hole, 20 countries including France, in addition to the EEC, signed the Vienna

---

[31] Related problems include fundamental questions about financial support of research, possible interests of the experts and the means of guarding against conflicts of interest or the necessary plurality of experts, none discussed in detail in this opinion.

[32] The final number of human cases has fortunately remained very far from the high range of these estimates.

[33] Molina, M. J. et F. S. Rowland (1974), "Stratospheric Sink for Chlorofluoromethanes: Chlorine Atom-Catalysed Destruction of Ozone", Nature, 249, 810-812.

convention for the protection of the ozone layer, a convention that encouraged exchanges of information, research, and monitoring. Nonetheless, no consensus was reached about a complete ban of CFCs, especially in view of their manufacturers' opposition to any ban except in aerosols. Only after the discovery of the hole in the ozone layer by Forman, Gardener, and Shackling[34] did 24 countries and the EEC sign the Protocol of Montreal in 1987. This accord was made progressively firmer and extended to new countries, until it finally included more than 100 countries agreeing to a schedule for the complete ban of CFC and halon production by 2030.

The risks of global warming were envisioned long ago, but only at the beginning of the 1960s did measurements at the Mauna Loa observatory demonstrate the increase in atmospheric CO2 concentrations in the Hawaiian Islands and at the South Pole. At the beginning of the 1980s, climate changes had become a political problem, with opposition between partisans and adversaries of strong action. The controversy led to the creation of the Intergovernmental Panel on Climate Change (IPCC). During the 1990s, recorded temperatures but also and especially observation of ice melting and ocean levels showed the beginning of planetary warming and confirmed the modeling results. The human origin of this warming was widely suspected, but scientists generally agreed that the cause-effect relation was uncertain. This ambiguity helped to block any effective decisions. In 1992, at the Earth Summit in Rio de Janeiro, 154 countries signed a convention that involved no restrictive measures. Agreements that included specific figures for the reduction of greenhouse gas emissions were signed in 1997 in Kyoto, but some countries, including the United States, finally refused to ratify it.

Only a small minority of experts today contests the cause of global warming. The scientific uncertainties now focus more on the scale and geographic distribution of the consequences. On the other hand, the costs of reducing fossil fuel consumption are perceptible, pressure groups are active, and the short-term interests of countries diverge. As the Copenhagen summit in December 2009 proved, it is still very difficult to reach an ambitious international agreement on greenhouse gas emissions.

In all these examples, it is notable that the potential existence of a risk was well recognized. Although the points of view expressing these doubt were initially a minority and not considered convincing, they relied on explanatory models and mechanisms, on experimental data and observations. Nonetheless, a complete evaluation of the risk was impossible.

It is possible, although more perilous, to cite examples of ambiguity today. The possibility of a causal association between the use of cell phones and some cancers, which we mentioned in section II.C, remains the subject of an unresolved debate characteristic of ambiguity. There is now, however, a consensus that the possibility of a risk cannot be ruled out. The possibility of a syndrome of people hypersensitive to electromagnetic fields is also mentioned and argued, in this case without even an agreement about the possibility of the risk. We might also mention nanomaterials and the ambiguity about the possibility of a specific and massive effect on populations. Finally, multifactorial risks have always been important in the history of epidemiology, and colony collapse disorder in bees is a recent and classic example (see sidebar 8).

In all these cases of ambiguity, uncertainty is focused on the reality of a causal association, and it appears that this question blocks decision-making mechanisms. That is, decision-makers are not receiving a distribution of the possible risk levels that would enable them to calibrate it with prevention. Instead they obtain a set of disparate scenarios that no scientific evidence can resolve. For example, there is one scenario where no risk exists and no action is necessary, and another where major harm will occur in the absence of strong and rapid intervention. The adoption of conservatory measures, based on an unfavorable scenario, does not meet the same criteria as under the prevention model. They must be based instead on a specific decision logic, that of the precautionary principle.

---

[34] Farman, J. C., B. G. Gardiner and J. D. Shanklin (1985), "Large Losses of Total Ozone in Antarctica Reveal Seasonal Cl0x/NOx Interaction", Nature, 315, 207 – 210.

Sidebar 8 : Uncertainty in cases of multifactorial risks: the example of bee colony collapse disorder

For 20 years now, substantial excess mortality has been observed in bee colonies, first in Asia and more recently in North America and Europe.[35] The scale of this condition, which has been named colony collapse disorder, has increased very massively. Various estimates indicate that the bee population fell by 30% or more in 2008 alone, in numerous countries (including France, Italy, the United Kingdom and the United States).[36] Nonetheless, the fight against this phenomenon has been hampered considerably by the uncertainty about its specific causes and by the failure of public authorities to react in view of this uncertainty. The case of France is illustrative.

When the first cases of this excess mortality appeared in France,[37] attention was rapidly focused on two insecticides: Regent TS (active ingredient: fipronil) and Gaucho (active ingredient: imidacloprid). Because the responsibility of these agents had not been demonstrated scientifically, the Minister of Agriculture applied the precautionary principle in February 2004 to suspend the sale of fipronil-based insecticides for all agricultural use. Gaucho was gradually withdrawn from the market.[38]

These initial measures were not supported by subsequent observations. At the end of a survey covering 2002-2005, the French Food Safety Agency concluded that the mortality observed in bees was not necessarily abnormal. Excess mortality (30-35%) was observed in only 8 800 hives, of the 1 350 000 in France. Fipronil was present in only six of these cases. In addition, the ban did not appear to reduce mortality. In 2005, an AFSSA opinion concluded that fipronil was harmless for humans, and in 2007, European experts decided to include it on the list of active substances authorized for pest control products in the European Union. In 2008, the Tribunal de Grande Instance (trial court) in Saint-Gaudens (Haute-Garonne) found no evidence of its responsibility for the collapses observed.

Nonetheless, in recent years, excess mortality has grown worse in France as in other European countries, although no single cause has been found. Experts today agree that the disappearance of bees is likely to be due to a combination of factors.

First of all, pesticides play a role, weakening the bees' immune systems, making them very sensitive to infections. New generations of pesticides currently available to farmers include the neonicotinoids, which are neurotoxic compounds. The best known are Poncho (active ingredient: clothianidin) and Cruiser (active ingredient: thiamethoxam). These products induce loss of orientation in pollen-gathering bees. In May 2008, after the destruction of 10 000 hives in southern Germany, the German government suspended authorization for Cruiser. Pollen analysis showed the presence of at least 5 and up to 35 pesticides in the collapsed hives. Nonetheless they were also found in healthy colonies, sometimes in even larger quantities than in the damaged ones.

Second, various biological agents are attacking the colonies: mites such as the varroa mite, which may be, according to one study, responsible for a reduction of 45% in the number of colonies worldwide from 1987 through 2006, American and European foulbrood (Melissococcus pluton bacteria), viruses, especially the Israeli acute paralysis virus (IAPV), fungi and other parasites.

Third, malnutrition associated with biodiversity loss may contribute to the weakening of bees. Intensive agriculture has turned farmland into immense crop ranges without hedges, or borders or flowering grasses and had thus reduced the availability and diversity of pollen.

---

35 AFSSA (2008), Mortalité, effondrements et affaiblissement des colonies d'abeilles, report updated in April 2009 ; Lattes, A. and B. Sillion (2006), "L'abeille, la mite et les insecticides", L'Actualité Chimique, 294, pp.6-10 ; Grixti, J. et al. (2009), "Decline of Bumble Bees in the North American Midwest", Biological Conservation, 142, pp.75-84.

36 COLOSS (2009), Proceedings of the 4th COLOSS Conference, Zagreb, 3-4 March.

37 In the spring of 2002, 3000 hives of a beekeeper in the Haute Garonne were destroyed in several hours!

38 From 1999 for sunflower treatment and from 2004 for corn.

Finally, other factors may be suggested, although less important. The Asian hornet, a new predator of European bees, has now been found in 13 French districts. The multiplication of electromagnetic emissions may disrupt the magnetite nanoparticles on bees' abdomens. A gene introduced in GMO culture and coding for an insecticide produced by the bacteria Bacillus thuringiensis destroys parasites. By an analogous mechanism, it may attack bees.

If these factors taken separately seem incapable of explaining the trends observed, their combination might well create sufficient synergy to induce this disorder. The uncertainty thus concerns the combinations likely to have synergistic effects. The suspected combinations have in common the presence of pesticides or chemical agents. Their association with the lack of dietary diversity might make pollen-gathering bees more sensitive to pathogenic agents. On the other hand, the results obtained by beekeepers who provide dietary supplements or sterilize their hives show that prevention can have a positive effect even in the presence of insecticides.

Recently, some governments have started to act on these advances in the understanding of colony collapse disorder. In 2008, the US Congress promoted an agricultural policy that plans for land where wildflowers can grow. In 2009, the French Senate developed a plan for bee preservation, providing for the development of an epidemiology and monitoring network as well as research on the effects of the chemical substances used on bees.

4. Advantages of formalization: The example of epidemiology

Epidemiologic research has been examining the issue of the plausibility of causal associations for more than 50 years now. The dominant approach on this question, although contested by some, is based on evidence of causality, as formulated by Bradford Hill. This evidence makes it possible to conclude that a causal relation exists between two phenomena that appear empirically to be correlated (see sidebar 9).

In some ways, Hill's criteria resemble the principal elements used by judges to determine the validity of a risk assessment: the specificity of the imputed effect, the consistency of the relation between the putative cause and the imputed effect, and the quality of the scientific reasoning. A conclusion that a causal link exists does not require that all the criteria be met: the association between exposure to ionizing radiation and leukemia, for example, is not at all specific. The conclusion, which therefore includes some subjectivity, can only result from the judgment of a group of experts, not from a single individual. It is assumed that a group opinion tends to be more objective than an individual's.

The conditions of admissibility identified by jurisprudence seem therefore to converge towards the criteria for the objective identification of a causal relation in other disciplines. This type of convergence between law, epidemiology, and statistics has been seen in the past, for example, in terms of liability law, and it has mutually enriched these disciplines. It opens interesting paths for the implementation of the precautionary principle, in terms of progress in dealing with questions that, for now, have no answers.

Sidebar 9 : Evidence of causality, according to Bradford Hill

In 1965, the English statistician and epidemiologist Austin Bradford Hill proposed the use of nine categories of empirical evidence to determine whether a statistical linkage between two variables could be interpreted as a cause-and-effect relation.[39] These "points of view", to use Hill's terms, were inspired by epistemologic reflection on the concept of causality, especially in Hume and Popper, and conceptualized the work by Hill and Doll to demonstrate the existence of a causal association between smoking and lung cancer in the British doctors' study.[40]

These "points of view" are:

- the strength of the statistical association

- the consistency of the observations

- the specificity of the effect observed in cases where the suspected cause is present

- the time sequence, that is, cause comes before effect

- the demonstration of a quantitative relation between cause and effect (similar to a dose-response relation)

- the plausibility in terms of scientific knowledge in general, and more specifically, that related to a mechanism of action

- the lack of contradiction with existing knowledge about the effect

- the existence of experimental data supporting the hypothesis

- the analogy with other recognized causal relations.

39 Hill AB. (1965). The environment and disease: association or causation? *Proceedings of the Royal Society of Medicine*, 58, 295-300.

40 Doll R, Hill AB. (1954). "The mortality of doctors in relation to their smoking habits". *British Medical Journal*, 328: 1529.

CHAPTER IV

Assessing the modalities and stakes

Section 1
An overlooked problem

At the conclusion of the phase of uncertainty assessment, it should be clear whether a public decision should be made according to the rules of standard prevention, prevention under uncertainty, precaution, or simple monitoring. The process of collaboration should have brought together "apparently solid and reliable scientific indications" supporting the different risk scenarios for the public decision-makers, who in many cases are then subjected to contradictory pressure for and against immediate action.

The need for a consistent framework for analysis, evaluation and justification of decisions in situations of this type is seen daily, for the rational application of the precautionary principle, justification of the absence of conservatory measures, reconciliation of the points of view of the individuals and groups concerned by a decision, etc. This observation applies even to the best known risks, such as those associated with some natural phenomena (see sidebar 10).

Sidebar 10 : The case of natural risks

Natural risks are a particularly fertile domain for questions that public decision-making under uncertainty must resolve. On the one hand, the government is directly concerned, first in determining the zoning or development of the area, necessarily taking these risks into account to prevent them (for example by preventing long-term construction in flood-risk areas) or reduce them (for example, by defining rules for earthquake-resistant construction in areas at seismic risk), or to ensure effective management in crisis periods. In these circumstances, clarification of the rules and improvement of the tools are particularly important.

In all these areas, the first responsibility of the government is to establish high-quality scientific knowledge and to ensure that this knowledge is shared by all concerned, especially the inhabitants of the geographic area affected by these risks, but also the local governments, companies, developers, insurance companies, and real-estate lawyers. It involves especially making the maps and geographic data public, indicating the nature of the risk with sufficient precision (scale of plots and buildings).

Regulatory zones can then be established, together with zoning and risk prevention plans to guide decisions for future development. That is, the first thing that public decision-makers should do in cases of natural risks is to reduce and if possible eliminate uncertainty. But in many cases, officials will have to deal with existing development, located in areas at risk, and will have to make decisions for these areas in periods of alert, which are also periods of uncertainty.

Two examples can be mentioned.

The first is the situation of flood plains, when strong local precipitation combines with storm warnings upstream from the watershed. When these alerts come shortly after a very rainy period that has saturated the water tables, sheet floods can occur together with the overflow of watercourses. It should be possible to model these phenomena and then to apply quantitative predictive management tools to them, but their rarity (once in a century) and the recent nature of scientific models means that calibration is not sufficiently precise at present, and both unnecessary evacuations and severe damage are possible. It is thus essential to be able to mobilize, in real time, an experienced expert advisory group able to advise the public officials. This assumes that full-scale practice drills have been conducted and that the list, means of communication, and availability of experts in the disciplines concerned and their intervention tools have all been checked in real time. Moreover, climate change is likely to increase and modify risks so that it is no longer possible to base these exercises only on the history of these phenomena.

Volcano eruptions are probably the emblematic natural risk. Three volcanos are active in French territory: Mount Pelée in Martinique, the Grande Soufrière in Guadeloupe, and the Piton de la Fournaise in Reunion. Although the latter has presented no particular problems in terms of uncertainty, the same is not true for the West Indian volcanoes. The eruption of the Grande Soufrière in 1976 was an excellent example of the difficulties of public decision-making under uncertainty. The memory of the prefect's errors during the catastrophic eruption of Mount Pelée in 1902 probably played a role in the decision, finally futile, to evacuate several thousand Martiniquais and keep them away from their homes for several months. The primary characteristic of this crisis, however, was the lack of rules and tools related to the respective roles of scientists and public officials, especially in terms of risk assessment and media relations. The evacuation ended only after a committee of international experts recommended it. This committee submitted conclusions including a recommendation to set up a permanent committee of volcano risk assessment. The High Committee on Volcano Risk Assessment (CSERV) was created in 1988, by decree n°88-208, and operated for several years. It brought together a panel of French and international scientists and experts and heads of the relevant government departments. Its twice-yearly meetings and its investigations abroad helped to provide operational feedback, to develop decision support tools, and to smooth out the expert functioning to enable better decision-making in a crisis period. The CSERV was dissolved by decree n°2006-662, dated 7 June 2006, which eliminated some committees to reduce public expenditures.

The clarity of the decision-making process requires that different aspects of the decision be clearly distinguished and that the decision be motivated by clearly identified elements and not some vague combination of factors. These elements are the costs and benefits at issue, their distribution in the population, the risk assessment, the uncertainty evaluation, the behavior of economic agents behaviors and their potential impacts on both the risk and the actions taken to prevent it.

The public decision-preparation procedure under uncertainty is often deficient, in particular in two areas. First, the issues are not completely or sufficiently characterized, especially the socioeconomic effects considered from the point of view of society as a whole. Second, the identification of stakeholders is also insufficient, as is their integration into a process of dialogue and review. Responses to calls by the Ministry of the Environment for research proposals on economic subjects tend to elicit little mobilization (and perhaps highlight the insufficient capacity) of the scientific community of economics researchers.[41]

These shortages are linked to an institutional void: although France is teeming with bodies that offer expertise and risk assessment, there is no body responsible for informing policy-makers about the choice of actions available to them. In particular, the identification and assessment of alternative measures for risk management are not included within the principal areas of statutory competence of the health agencies established by the laws of 1 July 1998 and 9 May 2001 (INVOS, AFSSAPS, AFSSA, AFSSET and IRSN).

In practice, however, this state of affairs has started to change, especially under the influence of European legislation. European regulation n° 1907/2006 concerning the Registration, Evaluation, Authorisation and restriction of CHemicals (REACH), for example, requires that in some cases proposals for restrictions by a Member State be accompanied and motivated by a socioeconomic analysis of the impact of such measures. A committee to conduct socioeconomic analyses was created, reporting to the European Chemicals Agency. AFSSET, representing France within this body, is responsible for defining the "priorities for the evaluation, authorization, restriction or classification and labeling" of such products.

Similarly, European regulation n° 726/2004, related to drugs for human use, established an

41 Bolo P. and de Bonvillers A. (2008), *Rapport d'évaluation des recherches en appui aux politiques publiques sur les risques liés aux inondations*, *(Report of assessment of research to support public policies on flood-related risks)* ISL Conseils pour le Ministère en charge de l'Environnement

obligation for applicants seeking a marketing authorization (AMM) to include the elements of a risk management plan and specific measures to limit environmental impacts. The French authorities responsible for issuing new drug authorizations are therefore required to assess the risk management plans, and AFSSAPS began to work on risk management in 2005.

Nevertheless, these advances are still too limited to invalidate the observed shortcomings stated above. On the contrary, they underscore its topicality.

Section 2
Toward systematic consideration of all relevant aspects of a decision

Public decision-makers must choose, based on their knowledge of an uncertain situation, an action among the range of possibilities, that will provide the greatest benefits to society. Decisions in the presence of uncertainty must therefore rely on an identification, as comprehensive as possible, of the existing range of actions and an evaluation of their impact, not only on public health and the environment, but also their short-term and long-term economic impacts.

The actions possible in a given situation of uncertainty are generally highly diverse. Consider, for example, a practice such as the marketing of a product or use of a technology whose hazardous or potentially hazardous character has been established. The measures available to the decision-makers in such a case include: unconditional authorization, authorization with conditions about the actual risk level, authorization with the implementation of a surveillance system of its effects, initiation of research or collection of data that might reduce the uncertainty, the definition of modalities to share or transfer the risk (compensation payments, insurance mechanisms, etc.), the imposition of a moratorium pending additional scientific results, a ban, etc.

In some cases, a measure taken against a risk may engender or aggravate other risks. Banning trichloroethylene, for example, led to its replacement by perchloroethylene at dry cleaners. The evaluation of the measures must therefore include both advantages and disadvantages, that is, it must consider simultaneously the risk considered, and the risks that public intervention might induce.

In situations of precaution as of prevention, the measures must be comparable for their efficacy, and the measure chosen must be proportional to the risks involved. This double requirement also assumes the fullest possible consideration of the costs and benefits for each measure considered, while integrating the variations possible due to individual behavior. In situations of prevention, the principle of proportionality requires a relation between the predictable cost of the chosen measure and its benefits in terms of risk reduction, the latter understood as a combination of probabilities and consequences. In situations of precaution, the principle is more difficult to grasp, since no complete risk assessment is available. Nonetheless, the cost of a measure must not be disproportionate to the scale of expected damage, and the measure must be provisional and revisable according to advances in knowledge. The flexibility of precautionary measures makes it possible to progressively ensure proportionality between costs and benefits as they become less uncertain. The conditions under which the principle of proportionality is implemented in situations of precaution must nonetheless be analyzed in greater depth within the different bodies concerned.

Decision-support tools have been developed in recent years to meet the challenge of evaluating such measures. They rely on methods similar to those of cost-benefit analysis, the principle of which is to assess the options available to policy-makers by attributing a value (generally monetary) to all of the consequences, be they health-related, environmental, economic, social, etc. Cost-benefit analysis simultaneously takes into account the risk and the temporal dimension of decisions by consistently integrating future and/or uncertain events using discount factors and probabilities of occurrence. Regardless of their nature, temporal horizon, and probability, all the factors relevant from the decision-making point of view can thus be aggregated into a single measurement, such

as the net present discounted value or the cost-benefit ratio. This value is supposed to measure the expected variation in social welfare associated with an option. The solution that provides the highest value for this measure is the one that can be considered the most advantageous from society's point of view.

There are some variants of cost-benefit analysis, especially multi-criteria analysis, with which decision-makers can set not a single objective (maximization of welfare), but several simultaneous objectives (for example, effective use of available resources including consideration of their redistributive aspects, and taking special societal values into account).

Today these tools have become common in various domains, especially regulation. In the United States, for example, since the adoption of the Regulatory Right to Know Act by Congress in 2002, the Office of Management and Budget at the White House has been mandated to use a cost-benefit analysis systematically to assess regulatory activity by federal agencies. "Regulatory impact analysis" is also applied in an increasing number of European countries as a necessary stage in the development of new measures.

Although these practices illustrate the importance that decision analysis methods can acquire in public policy development, they are not directly transposable to situations of uncertainty in which several risk scenarios coexist and are difficult to decide between. These tools depend on the existence of a probability distribution that sums up the state of knowledge in the face of a situation of uncertainty. Their application to problems where such a distribution cannot be defined unequivocally requires an in-depth methodological analysis.[42]

A second weakness of these methods, at least in their standard applications, is their lack of consideration of agents' behavior in the face of uncertainty and under the options envisioned. Just as it may be necessary to assess risk a posteriori after having assessed it in the laboratory, to take into account the actual conditions, human behavior must be integrated into the cost-benefit analysis. Concretely, it is thus necessary to take into account the interplay between stakeholders, the elasticity of the reactions of producers, consumers or users, and their understanding or misunderstandings, etc.

Finally, it is necessary to pay special attention to the distribution of costs and advantages in the population. If the net costs borne by a given social category are substantial, while the mean cost for the population is supposed to be low, the acceptability of the measures requires additional resources or the diminution of other constraints.

[42] Recent developments in decision theory are opening promising pathways. See for example Cohen, M. and J.-M. Tallon (2000), "Décision dans le risque et l'incertain: l'apport des modèles non-additifs", *Revue d'Economie Politique*, 110(5), pp. 631-81.

Section 3
A framework for participation in decision-making

Cost-benefit analysis has often been used as a black box that, filled with the necessary data, provides an economic or scientific verdict on the procedure to follow. This usage is a serious problem for decisions about risk, especially when uncertainty is high.[43] Nonetheless, these same methods can serve as an excellent framework for the collective construction of decisions. To do so, they must be used openly, in a process alternating between public and expert consultations, similar to that described in the first section. Quantification, which is the foundation of cost-benefit analysis, must serve here as the spur to collect all the pertinent information and describe it objectively, even when it is difficult or impossible to quantify.

The risk management process involves individuals and social groups that do not face the same costs or derive the same benefits from the existence of the risk. Any management decision is therefore a tradeoff between these costs and these advantages, and this should be stated explicitly (see sidebar 11). As we have seen, the legitimacy of a diversity of viewpoints in situations dominated by uncertainty must be explicitly recognized.

The positive or negative value of a measure for a social group therefore cannot be evaluated only from above, but requires that the points of view of all the stakeholders be collected. For example, the value of a treatment that prolongs life for several months but with severe side effects, and which is the pride of its inventors, cannot be determined from only one point of view.

In societies that pay increasing attention to risks and respond much faster to the flow of information than in the past, consideration of the distribution of the stakes and points of view within the society is an essential element of risk management. Disregarding these aspects and basing management solely on scientific knowledge can cause some stakeholders to organize against those responsible for risk management and promote mistrust and excessive reactions, even when the decision is justified from the viewpoint of mean costs and advantages. The decision-preparation process must therefore be designed as a meeting point for rational discussions between diverse opinions.

Sidebar 11 : EU decisions on dioxin concentrations in food products

Dioxins comprise a family of environmental contaminants including 210 molecules with the same mechanism of action but with different levels of toxicity. The toxic effect that the World Health Organization (WHO) considers to be critical for human health, that is, likely to be induced at the lowest exposure doses, targets the reproductive system. This toxic effect has been observed in animals and their no-observed-adverse-effect level (NOAEL) doses were transposed to humans using safety factors, to reach a threshold for tolerable human exposure of 14 picograms per kilogram of body weight per week (14 pg/kg bw/week).[44] To take the different toxic potentials into account, WHO has established "equivalency factors" for the 29 major congeners in relation to the most toxic congener. To assess the risk for a given population, the threshold of 14 pg/kg bw/week is compared with the sum of concentrations of the different congeners to which the population is exposed, weighted by the toxicity equivalency factors.

Because human exposure is very largely foodborne, the European Food Safety Authority (EFSA) evaluates and the European Union Directorate-General of Health and Consumer Protection (DG SANCO) manages this risk on behalf of the member states.

[43] World Health Organization (2005), *Dealing with Uncertainty*. Report of a WHO meeting, Copenhagen, Denmark, 15-16 December.

[44] Scientific Committee on Food (2001), *Opinion on the Risk Assessment of Dioxins and Dioxin-like PCBs in Food*, CS/CNTM/DIOXIN/20 final. European Commission, Brussels.

The results of the risk assessment showed that a substantial proportion of European consumers (on the order of 10%) are regularly exposed to doses above the tolerable weekly intake for dioxins. Moreover, setting standards that resulted in exposure below 14 pg/kg bw/week for high consumers would result in eliminating a considerable quantity of foods from the market.

Dioxins are thus a case where uncertainty about health risk is high (transposition from animals to humans), while the economic consequences of risk reduction measures are close to certain, strong, and widespread (all food of animal origin may be concerned: meat, fish, milk and dairy products).

It would be difficult for risk management measures in these cases to be based on consumer information, which would have to be very complex. Nor can they be based on a modification in production practices since dioxins are environmental contaminants that depend on pollution of the production site and not on the practices themselves. DG SANCO therefore chose a dual approach, both encouraging the limitation of dioxin emissions by industrial and municipal waste incinerators and setting thresholds, specific for each category of food. Exceeding the thresholds can lead to corrective action. The thresholds are maximum limits, above which the products are considered unfit for human consumption, withdrawn from the market and destroyed. These maximum limits are thought to involve more than 1% of the food sold in the European Union. Finally, action thresholds were established, which would not necessarily result in product withdrawal but would allow national authorities to take action. An unusual number of analytic controls above these thresholds can serve as an alarm signal and encourage national officials to identify a specific source of pollution and to reduce it. These thresholds are likely to concern at a maximum 5% of the samples tested. Finally target levels were to be established in 2008 to reflect a pollution level at which the entire EU population would be exposed to levels below the tolerable weekly intake of 14 pg/kg/week. Member States had difficulty accepting these thresholds, because they identify, even if they do not eliminate from the market, nearly 50% of the food of animal origin, for which dioxin levels are remarkably high.

This example shows very clearly how risk managers can act in the face of substantial uncertainty about harmful human health effects. It has led to innovations in risk management tools and involves the implicit consideration of a cost to industry/cost to health ratio.

Applied in a broader framework, decision analysis tools can be used to structure such a process with precision. They can compare the opinions of different stakeholders and clarify the points of divergence. In cases of strong uncertainty, where the simple consideration of a risk scenario cannot suffice, they can serve as markers for the stakeholders with, for example, optimistic, intermediate, and pessimistic scenarios. In cases where the participants emphasize different aspects of a problem, the structuring process itself can be the principal contribution of the analysis, by clarifying the specific elements of a decision-making context that can in turn engender innovative risk management solutions.

On this point, as for the consideration of uncertainty, a methodological analysis of the tools must precede their implementation. Given the wealth of experience on this theme, however, what matters most here is to define good practice principles, which can be based on those guiding the health risk assessment: independence, excellence and transparency.

The stakeholders identified at the first stages of the decision-preparation process, which are principally the social groups for which a potential risk exists, are not the only ones concerned by the consequences of the decision implementation. For example, decisions about reducing smoking have consequences for the owners of shops selling cigarettes. For each decision option, it is important to identify the social groups whose lives will be influenced by its implementation, not only in terms of risks, but also in terms of changes in living and working conditions, income, etc. The representatives of these stakeholders should participate in the evaluation of the different options.

The enumeration of the possible options and the evaluation of their advantages and disadvantages must, as indicated above, alternate between consultations with all the stakeholders and scientific,

technical and economic assessment of their feasibility and their potential effects.

The investigation of the advantages and disadvantages of different options must also review in greater depth the consideration of the temporal dynamics discussed in section II.C. It must, in particular, distinguish measures that can be implemented rapidly and which are likely to be acceptable; those that require substantial technical preparation, significant financial investment, or the implementation of major organizational changes; and finally those that require changes in behavior, and hence a significant amount of time for preparation, training, and support.

Finally, the decision must include provisions for monitoring and reassessing the risks and reviewing the management measures. It must specify under what conditions its validity will be reconsidered, and according to what procedures it can be suspended or modified if these conditions are met. It must also specify the period beyond which the measures taken must be reviewed and possibly revised, even in the absence of an important change in the situation or knowledge.

APPENDIX 1 : TEXT OF THE REFERRAL

Mr. Chairman,

The precautionary principle, inscribed in the Constitution since 2005, has elicited questions about its implementation.

Some think that the introduction of the precautionary principle into the French constitution may lead to its excessive use and may thus serve as an obstacle to scientific research and block both technological innovation and economic initiatives. On the other hand, for others, the precautionary principle must be above all interpreted as a principle of responsibility for actions, requiring application of a tested method of risk assessment, based on scientific rigor.

These questions were discussed recently during a public hearing held by the Office parlementaire d'évaluation des choix scientifiques et technologiques (Parliamentary office for the evaluation of scientific and technological choices, OPECST). You participated in the assessment of the application of the precautionary principle four years after its inclusion in the constitution.

The president of the Assemblée Nationale (National Assembly) has announced an evaluation of the implementation of principle as part of the work of the Comité d'évaluation et de contrôle (CEC) des politiques publiques de l'Assemblée (National Assembly committee for the evaluation and monitoring of public policies).

From this perspective and to continue your analysis on this subject, we ask your Committee to develop a methodological analysis aimed at clarifying the issues and procedures for public decision-making in situations of uncertainty, especially when it involves implementation of the precautionary principle.

Your opinion should, in particular, specify the relevant situation for the application of the precautionary principle, propose instruments making it possible to improve the choices available to policy-makers in the domains where society faces an uncertain risk—especially in the field of environmental health—, and to point out the reasons for its erroneous invocation (for example confusion between precaution and prevention in situations involving prevention).

In the recommendations that Committee for Prevention and Precaution will submit, we ask you to consider in particular the continuity of decisions between situations in which the risk is relatively well known and others where uncertainty dominates.

Finally, we would like your report to discuss in detail how the practical implementation of the precautionary principle can be organized. We would like to receive this report during the first half of 2010.

Please accept our best wishes.

Jean-Louis BORLOO Chantal JOUANNO

APPENDIX 2

PRINCIPAL CONCEPTS

Uncertainty: nature of a situation that cannot be characterized as precisely as one would desire

Risk: given by all of the possible outcomes of the situation, the consequences and the associated probabilities of occurrence; simplest representation of uncertainty

Risk Assessment: description of scenarios of the occurrence of a hazard and of the occurrence of its effects, and estimation of the associated probabilities and harm

Prevention framework: framework of public decision-making when risk management measures can be based upon an assessment of risk

Margin of uncertainty of the risk: all of the risk estimates admissible from a scientific point of view under the prevention framework

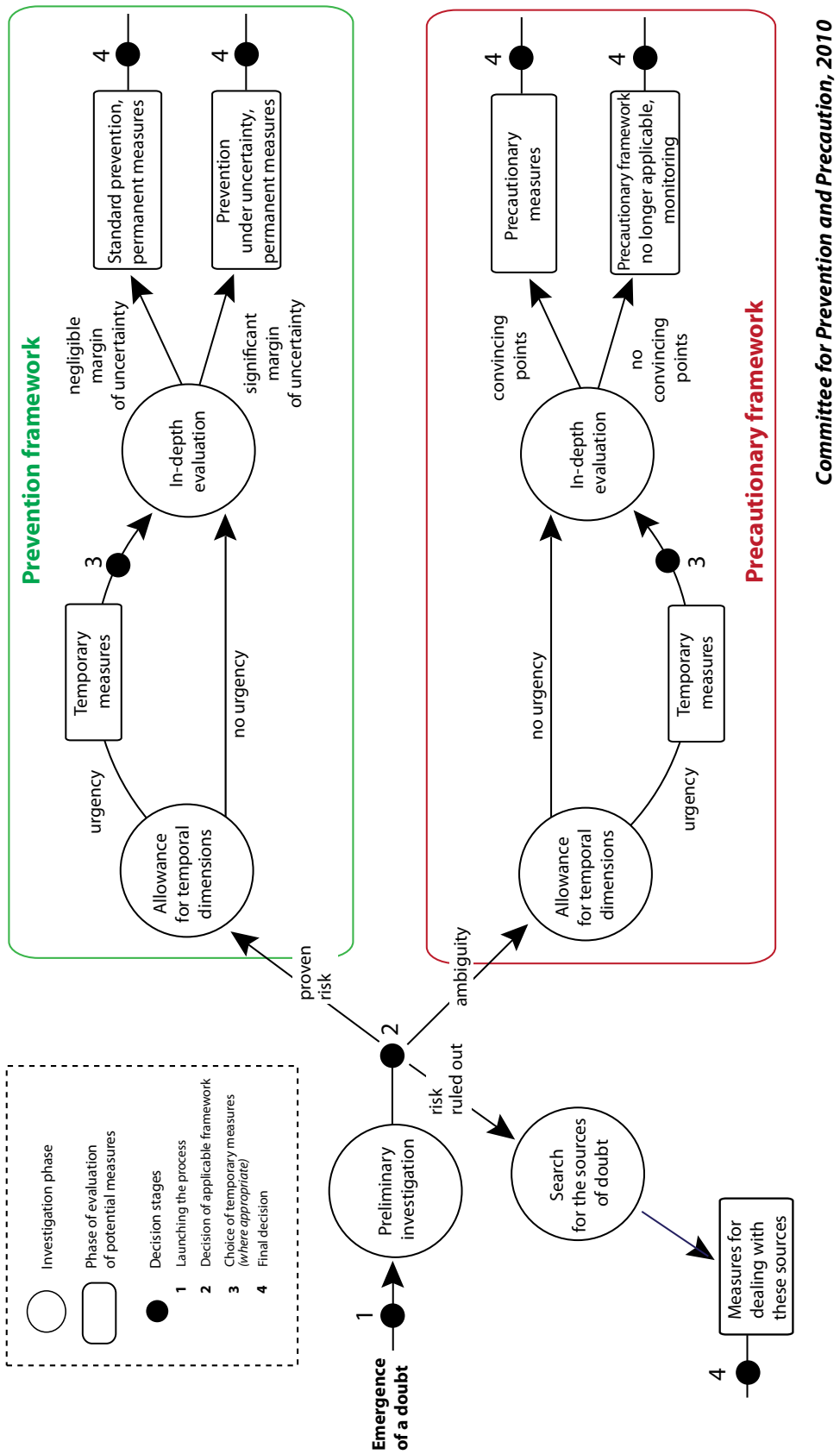
Ambiguity: situation of extreme uncertainty where representation in the form of risk is impossible (e.g., it cannot be determined whether the hazard exists or not)

Precautionary framework: framework of public decision-making in the presence of ambiguity

Public decision-making in situations of uncertainty: choice to take public action to prevent or to reduce potential harm, and, where appropriate, the choice of modalities of this activity

ANNEXE 3

A SIMPLIFIED REPRESENTATION OF THE PREPARATION PROCESS FOR PUBLIC DECISION-MAKING IN SITUATIONS OF UNCERTAINTY



Committee for Prevention and Precaution, 2010

Missions of the CPP

Created by a Ministerial decree of July 30 1996, the **Committee for Prevention and Precaution (CPP)** is composed of eminent scientists specialized in the fields of environment and health.
Its funding and its secretariat come from the Ministry of Ecology, Sustainable Development and Energy.
The Committee has enacted ethical rules to govern its internal operations.

Its work and its recommendations to the Minister have a three-fold mission:
- to help ground the policies of the Ministry of the Environment in the precautionary and prevention principles;
- to monitor, warn about and offer expertise for health problems associated with environmental disturbances;
- to link research and scientific knowledge with regulatory action.

The CPP may examine subjects referred to it by the Minister or on its own motion.

C O M I T E
de la PRÉVENTION et de la PRÉCAUTION

For further information :

Secretariat of the Commitee for Prevention and Precaution
Ministry of Ecology, Sustainable Development and Energy
CGDD, DRI, SR
Tour Voltaire
92055 La Défense Cedex

website :
http://www.developpement-durable.gouv.fr/Le-comite-de-la-prevention-et-de,15001.html
e mail :
dominique.thierry1@developpement-durable.gouv.fr

Commissariat Général au Développement Durable
Direction de la Recherche et de l'Innovation
Service de la Recherche

Liberté • Égalité • Fraternité
RÉPUBLIQUE FRANÇAISE

Ministère
de l'Écologie,
du Développement
durable
et de l'Énergie

Réalisation : La Balise Bleue 09 51 44 11 58