E. HANAK, E. BOUTRIF, P. FABRE, M. PINEIRO, (Scientific editors), 2002. Food Safety Management in Developing Countries. Proceedings of the International Workshop, CIRAD-FAO, 11-13 December 2000, Montpellier, France, CIRAD-FAO. CIRAD CD-ROM, Montpellier, France.

Prevention, Precaution, Consumer Involvement: Which Model for Food Safety in the Future? [1]

B. CHEVASSUS-AU-LOUIS

French Food Safety Agency (AFSSA), 23, avenue du Général de Gaulle,
BP 19, 94701 Maisons-Alfort Cedex, France. Email: bchevass@jouy.inra.fr

Abstract

Until recently, regulatory authorities in developed countries used a "standard" model for analyzing health risks from food, developed to investigate other technological risks. We will begin by reviewing the characteristics and principal options of that model. Since the early 1980's, a number of reported dysfunctions in the food chain have caused public opinion in several countries to become increasingly skeptical about the model's value. The precautionary principle was therefore suggested as a new guideline for reducing risk from food. We shall review the impact that this has had on risk management, based on the "appropriate" definition of the precautionary principle which is currently emerging in Europe. We shall then turn to the risk assessment process, in order to show how new demands by decision makers for a rigorous application of the precautionary principle have significantly affected the assessment process itself. In closing, we shall examine the "standard' view of communication on risk, which is seen as the final stage in the analysis of risk. We shall demonstrate how active participation by representatives of the public at the evaluation and management stages can improve both the quality and the acceptability of the analysis of risk. The application of the precautionary principle thus affects not just one aspect of the analysis of risk, but all three. Considered together, the changes it brings make it possible to propose a so-called "constructivist" alternative model which, in the case of food safety, can contribute to a better acceptance by society of the rare but inevitable malfunctions in the production of foodstuffs.

Introduction

At the outset, we wish to suggest a definition applicable to the overall objective of the analysis of risk. Under a democratic system, the purpose of a system for analyzing risk is to provide a social environment for individuals in which risks which give cause for concern are perceived, acknowledged and effectively reduced to a socially acceptable level by decision makers, and risks of which they are unaware are adequately monitored so that they can be detected and timely warnings issued.

In this perspective, since the 1950's, most industrialized countries have created institutions responsible for assessing the various aspects of food safety affected by changes in ingredients, processes or the production of agricultural commodities. Until recently the analysis of risks was conducted in accordance with a "standard" model designed to review

[1] Article originally presented at the OECD Conference on the Scientific and Health Aspects of Genetically Modified Foods, Edinburgh, 28 February – 1 March, 2000.

other types of technological risks. The features and the principal options of this model will be discussed below.

Since the early 1980's, reported dysfunctions in the food chain that could be seriously detrimental to human health have caused public opinion in several countries to question and become increasing skeptical about the model's value. The precautionary principle, which was originally articulated and implemented to deal with environmental risks, was suggested as a new guideline for assessing food safety. We will review its impact on risk management, using as a reference point the "proportionate" definition of the precautionary principle that is currently emerging in Europe.

We shall then turn to the risk assessment process in order to show how new demands by decision makers for a rigorous application of the precautionary principle have significantly affected the assessment process itself.

In closing, we shall examine the "standard" view of communication on risk, which is considered the final stage in the analysis of risk. We shall demonstrate how active participation by representatives of the public at the assessment and management stages can help improve the quality of the analysis of risk as well as contribute to a better acceptance by society of the rare but inevitable malfunctions in the production of foodstuffs.

The Standard Model and its Options

The "standard" model for the analysis of risks is based on several theoretical or operational options which need to be briefly reviewed here so that we can better understand their contingent nature.

The first option is that of case-by-case assessments. In the case of GM foods or food additives, each situation is examined separately, the underlying assumption being that the factors add up to an aggregate impact, in other words that the combined use of several genetically modified foods or additives will have an effect that is close to the sum of their individual impacts. More specifically, any interactive effect is considered minor and within the safety margins applicable to the assessment of individual risks. This approach works well in the case of direct, simple (i.e., limited as to the number of clearly identified possible causes) and independent risks. It enables experts to work in a "continuous" manner, since the appearance of a new factor does not mean that the entire system has be reconsidered.

The second option is to only consider proven hazards, namely those whose causal links to adverse effects have been scientifically demonstrated and accepted by the scientific community as a whole. Hence, risks are assessed exclusively by scientists, who only take into consideration links which have been scientifically examined and shown to exist. Since the list of hazards is arrived at by consensus, the debate tends to focus mainly on the probability of occurrence and exposure. The "measure" of a risk is therefore generally expressed as a quantity (number of deaths, financial losses) resulting from an analysis of probabilities.

The third option entails a risk assessment phase which is clearly separate from risk management. One of the consequences is that assessments are often predicated on the assumption that any resulting management and control measures will be flawlessly implemented. We shall use the term "asymptotic risks" to describe these minimum risk levels.

A fourth option is that experts assess only risks and do not evaluate possible benefits from an innovation, or compare costs and benefits. This makes political decision-makers implicitly responsible for taking such additional considerations into account, without any indication being given as to how to conduct such a costs-benefits study.

Lastly, in terms of communication on risks, the model considers that while experts assess "actual" risks, society's perception of risks (the "perceived" risk) is more approximate and is inevitably affected by subjective factors. The purpose of information about risks is therefore to reduce this distortion by causing people to become aware of actual risks.

The standard model can therefore be described as:

- positivist, since it is entirely and exclusively based on indisputable scientific information;
- quantitative, since its risk assessment is expressed as an order of magnitude;
- reductionist, since it is limited to measuring the technical risk in the absence of human error (asymptotic risks) and, at the same time, assumes that risks can be added up, disregarding the effects of interaction among them;
- technocratic, since it essentially based on technical assessments and the public at large is entitled merely to receive information.

The Crisis of the Standard Model and the Emergence of the Precautionary Principle

During the 1980's several health crises occurred in medicine (contaminated blood), food (bovine spongiform encephalitis (BSE), listeriosis, dioxin, etc.) and the environment (asbestos, Seveso, etc.). In addition to their political and social dimensions, these crises were also indicative of crises in expertise, as the events concerned seem to have been underestimated or even disregarded by specialists. Several causes can be ascribed to this failure of expertise:

- In certain fields, the pace of research can lag behind that of innovation. KOUIRILSKY and VINEY (1999) believe for instance that only 7 per cent of all chemical molecules have been properly assessed in terms of their impact on health or the environment. Many relationships are still at the working-assumption stage and in many instances it will take some time before they are validated (as in the case of the effects of asbestos, or the human transmission of BSE). Increasingly frequent controversies resulting from disagreements among scientists (on the impact of hormones or transgenic foods, for instance) underscore the extent to which scientific knowledge is imperfect and challenge the notion that scientific information is consensual and indisputable.
- The asymptotic nature of risk assessment by experts amounts to a de facto disregard of risks linked to the practical circumstances of human activity. The risk associated with recycling spent oil was intrinsically low if recycling had been performed perfectly; bovine meat may not carry any risk of BSE communication if the hazardous tissues are properly removed, etc. In addition, it is evident that, in the case of many technological risks, their purely technical dimension is a negligible risk factor by comparison with the risks resulting from the interaction between humans and technology: in transport and nuclear energy, what is referred to as "human error" is blamed more frequently than equipment failure. Given that this dimension outweighs others, should it not be implicitly included in risk assessment and should not technical

systems as a whole be looked upon as “hybrids of humans and machines” (LATOUR, 1994)?

- Little attention is paid to the impact of interactive and systemic factors, because assessments are conducted on a case-by-case basis. This may be another reason why risks have been underestimated. For example, the emergence of multiple resistant bacteria immune to antibiotics has become a serious public health issue, even though all antibiotics were properly and individually tested before being approved. The unintended selection of such “improbable” bacteria resulted from the combined and uncoordinated use of these antibiotics. The matter of risks associated with the simultaneous or successive planting of GM crops within a given area raises issues of the same order and cannot be resolved by simply examining the properties of each genetically-engineered organism.

Coincidentally with these external and empirical criticisms of assessments, an endogenous scientific examination has been developed, aimed at the method’s ability to properly evaluate the behavior of complex phenomena whenever these occur under circumstances that differ significantly from of those in laboratories. The limitations identified by scientists themselves include:

- The taking into account of long-term factors. The theory of non-linear dynamic systems, popularized by the notion of deterministic chaos, shows that long-term changes in such systems is absolutely unpredictable beyond a given time horizon, whenever a minute change in initial conditions radically changes the end situation. This is the well-known image of the fluttering of a butterfly wing causing a hurricane, and it is unfortunately difficult to establish a priori whether even a relatively simple system is governed by such dynamics.[2]

- The taking into account of heterogeneous areas, in which certain processes cannot be anticipated using simple statistical environmental parameters (average density) and therefore require real-world empirical studies. This would apply, for instance, to the spread of forest fires or the downward leaching of pollutants in soil. In food safety, the issue is the proliferation of bacteria in an environment with a complex texture (and the resulting measure of shelf-life), or the spreading of pollen from transgenic crops in a real ecosystem. Here too, there are non-linear factors, in particular threshold effects, as processes can change significantly in response to minor changes in environmental parameters.

- Extrapolation problems, such as with assessing the impact on humans of small doses of a chemical or organic substance, when evidence is available only from animals and a few accidental exposures to high doses by humans. Depending on whether a linear or non-linear model is used, and whether it passes through the origin[3] or not, perhaps even with paradoxical and positive effects in small doses[4], the consequences for the assessment of risk will differ significantly, even though neither model can be validated based on existing data. Related to the extrapolation issue,

[2] One of the simplest examples of systems that are unpredictable over the long term is the fate of more than two bodies in a gravitational field, such as the solar system.

[3] If the assumption is that there is a minimum level of exposure which is harmless, the amount of the dose at that level can be represented by the point where the right-side dose/effect regression intersects with the x-axis. If, however, the assumption is that, as in the case of carcinogens, there is no harmless dose, the dose/effect regression is a straight line intersecting with the origin. In the former instance, changes in residual amounts below the minimum dose are supposed to be harmless. In the latter case, on the other hand, such changes are likely to affect morbidity levels.

[4] This is a assumption made in the case of small doses of ethanol, for example (BERGER et al., 1999).

scaling problems, even in simple situations such as the testing of models in wind tunnels, seem to obey laws that must be defined on a case-by-case basis, using more than just proportionality assumptions. Still more complex is the matter of changes in organizational level, in particular in biology, which has been shown to generate particular properties that are otherwise unpredictable on the basis of a description of the previous level, regardless of how exhaustive it may be. Among the simplest examples is that of a water molecule, whose properties (in particular in the liquid state) cannot be inferred from the properties of hydrogen and oxygen atoms. Likewise, it is impossible today to anticipate the tertiary structure – and hence the reaction properties – of a protein, based exclusively on the observation of its primary structure (the amino acid sequence).

Issues having to do with long-term impact, heterogeneous areas, low doses, scaling and, more generally, the predictive limitations of science for answering practical questions raised by decision-makers have turned out to be of particular concern in the environmental field, which is probably why the precautionary principle was initially developed there. However, the principle does not amount to a disavowal of science and a resurgent argument in favor of arbitrary political decisions. On the contrary, it calls for “more science”. Its many definitions make at least one common claim, namely that scientific uncertainties cannot serve as an excuse for decision-makers to do nothing. This means that uncertainties, rather than remaining exclusively within the purview of scientific research until they may become certainties, must instead be taken into account by decision-makers and serve as a basis for action in the manner explained below.

Arriving at a Decision “Based on the Precautionary Principle”

There are many ways of stating the precautionary principle. They can be divided into two categories – the radical version, which always results in bans whenever doubts remain, and the proportional version, which requires action but does not dictate what kind of action must be taken.

The radical interpretation will be mentioned here only in passing. It is based on the notion of the reversal of the burden of proof, that is, the obligation to ban any innovation until it has been proved harmless. If the preceding objections concerning the intrinsic limitations of the scientific approach are accepted, it becomes evidently just as pointless to demand proof of the existence of a risk as of its absence. Paradoxically, therefore, radical interpretations of the precautionary principle are just as positivist and reductionist as the standard model.

We shall therefore examine here the notion of decisions based on a proportional implementation of the precautionary principle, which is gradually gaining support in Europe. It is described in particular in KOURILSKI and VINEY (1999) as well as in the recent (February 2000) Communication from the European Commission and has as its underlying assumptions the four “pillars” of proportionality, consistency, reversibility and comparative analysis.

Proportionality

If we rule out imposing a ban whenever uncertainties remain, we must then examine a wide spectrum of possible decisions, ranging from a ban to leaving things as they are, possibly along with measures to ensure that effects can later be traced (see the point below on reversibility). In order to make a choice among possible decisions, the strictness of our approach must somehow be made proportionate to the nature of the potential risk. Besides

the seriousness of the impact on individuals (whether there is mortality risk in the case of health exposure), a risk's aggravating factors would include:

- its irreversible nature (e.g. the disappearance of species in the case of transgenic foods or the incurable character of a condition such as BSE);
- its deferred impact (which may be felt by future generations, as in the case of nuclear risk);
- its catastrophic potential (number of potential victims).

Consistency

Care must be taken to ensure that decisions made further to the precautionary principle are consistent and do not discriminate among potentially competing economic entities. Thus, if restrictions are imposed on the use of a product based on the precautionary principle, the same measure should apply to all similar products suspected to be equally hazardous. Likewise, in order to prevent trade distortions, discrimination based on the geographical origin of products may be justified only of it can be demonstrated that the risk factors considered under the precautionary principle are specific to a region. Lastly, a decision based on the precautionary principle should not be more severe than one concerning a similar, proven risk and causing the prevention principle to be applied.

Reversibility

The notion of reversibility takes into account the changing nature of uncertainty. It considers that the application of the precautionary principle should not be limited to an acknowledgement of the uncertainty but should instead be combined with active measures designed to make the situation evolve. Two of these measures are of particular importance:

- the support of research, aimed at narrowing the scope of uncertainties and hence, over time, providing grounds for better decisions; this issue has been taken up in particular by the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). Much of the work on decision-making theory underscores the value of investing in research, and a method of analysis has been suggested to provide guidelines for it (value-of-information or VO analysis – see especially GRAHAM, 2000)
- the creation of an efficient monitoring system that would make it possible to complement the initial assessment with a body of post facto data on possible malfunctions; the monitoring system could make use in particular of the increased traceability of products, as in the case of drug monitoring of human and veterinary medication. In this perspective, informative labeling would seem to be one way to promote traceability, although other options may be considered (identification of batches and monitoring at all stages of manufacturing).

Comparative Character

Whenever several alternatives are available, the issue of the best choice arises, hence that of the effectiveness of the measures taken. This is where the cost/benefit analysis comes in. Its purpose is not just to analyze the situation in terms of economic costs and benefits, as

would an insurance company. Although this aspect clearly can be considered, the factors that must be examined here are more complex, since the decision is made by a government authority and does not concern a theoretical private investment. These factors will have to include the degree of protection that is demanded by the public (determined in part by cultural factors), the acceptability of measures (on which their effective implementation depends[5]), and considerations of an ethical nature (the transformation of species, in the case of genetic engineering, animal welfare, etc.), and may include considerations of non-commercial value, especially as regards environmental impact.

The concept of cost/benefit analysis (introduced in Europe some years ago, at the time of the debate over the "fourth criterion") may appear as the refuge of arbitrary rule. Concern over this is sometimes expressed by both sides to an issue. Some consumer groups view it as a way of "compromising with risks", by approving insufficiently assessed innovations in the name of economic considerations; on the other hand, private business sees in it a danger that products presenting a minimal risk may be banned, ostensibly on the grounds that they are not useful, although usefulness is for market forces to determine. Two observations need to be made in relation to both concerns:

- Given that scientific progress is bringing to light increasingly subtle effects (as in the case of small doses of chemicals) and identifying factors that often work in very indirect ways (such as the multiple causes of climate change[6]), the notion of the absence of risk, if it ever existed, applies to an ever shrinking field. Offsetting positive impacts must therefore be shown to exist in order to justify the approval of new products. The current situation of GM foods in Europe seems emblematic of this issue: either all potential dangers are denied on principle and the debate starts again whenever a potential risk is detected (genes indicating a resistance to antibiotics, the toxic effect of plants on butterflies, etc.), or else it is agreed that the innovation should be examined in cost-benefit terms in light of current farming methods, so that certain GM crops may, in time, be introduced in certain agricultural and food systems.
- This approach has been applied from the outset to drugs. Biologically active substances almost always have multiple effects, including some that are undesirable, so that only a review of their therapeutic value in relation to possible contraindications can justify their approval. The marketing authorization can be rescinded whenever drug monitoring discloses harmful effects, a consideration which argues in favor of traceability, even when a time-tested system of prior-assessment exists.

Having identified the various factors that enter into decision-making and risk management based on the precautionary principle, we shall now discuss the consequences for the risk evaluation phase. The position has been taken in some quarters that the option of applying the precautionary principle is a matter of concern for decision-makers only, and that the role of scientific evaluation has not been affected. We wish to show here that, on the contrary, risk assessment will come under additional pressure.

[5] This is particularly important in the case of health risks from food, which involve a large number of economic agents who are *de facto* responsible for risk management. Drastic measures that are unlikely to be fully implemented may not be as effective as less restrictive ones endorsed by the sector.

[6] Including the role of rice paddies, termites and ruminants in climatic warming because they produce methane, a greenhouse gas.

The Precautionary Principle and Risk Assessment

The four “pillars” defined above call for the use of a significant amount of data, in order to arrive at the best possible measure of uncertainty and its possible consequences, and for making comparisons among the options available to decision-makers. That is why the application by decision-makers of the precautionary principle has a significant impact on the actual assessment of risk. We shall examine here in particular the consequences for the identification of hazards, the measurement of the degree of uncertainty, the analysis of benefits and the organization of monitoring.

The identification of Hazards: A Broader Vision

Among the shortcomings attributed to the “standard” model described above s its inability to take into account weak factors, indirect links or systemic effects whenever the existence of such complex determinisms cannot be demonstrated by an analytical and experimental approach, geared to the study of the impact of a small number of independent factors over a limited time. If these effects, whether positive or negative, are to be taken into consideration by decision-makers, as exhaustive as possible an inventory must be taken of them, which must take into account all minority or non-conventional opinions, so as to ensure that it is as extensive as possible prior to undergoing a critical analysis. The possible consequences of changes in the processing of animal feed or the recycling of spent oil constitute, for the BSE and dioxin crises, examples of innovations where a broader investigation of hazards may have led to precautionary measures.

The introduction of multidisciplinary approaches also represents a method for perceiving the limitations of a consensus within a single discipline. For example, in the case of genetic engineering, molecular geneticists are particularly sensitive to the quality of the genetic base but not to the indirect impact on ecosystems, to which ecologists pay considerable attention (the reverse is also true); similarly, the principle of substantial equivalencies, applied to ensure the harmlessness of genetically engineered substances, is more readily acceptable to chemists and toxicologists than to nutritionists. It is also in this context and for these very reasons that it becomes advisable to allow representatives of society at large participate in assessment procedures, as discussed below.

Quantifying Uncertainty: The Plausibility Concept

Once the hazards have been identified, a critical analysis must be performed and a classification made. Under the “standard” model, the sorting out process is simple: only hazards that have been proved to be harmful are taken into consideration, that rule being related to the scientific consensus on the existence of indisputable data to justify preventive measures. Once the uncertainty factor is taken into account, the examination must be broadened to distinguish between hazards that have some degree of likelihood from those without any basis in fact. Our suggestion is that the concept of the “plausibility” of an assumption should be introduced here to refer to this degree of likelihood and to distinguish it from the notion of mere probability, used in the “standard” model to describe the frequency with which a proven hazard occurs.

This distinction is necessary because it concerns two separate aspects of uncertainty. Highly plausible assumptions (such as the current linking of BSE to new human forms of the Kreuzfeld-Jacob syndrome) can coexist with low probability rates (in terms of deaths per exposed individual); conversely, hypotheses that were not very plausible at one time can,

over the longer run, prove to apply to virtually all individuals concerned (e.g. the link between HIV-seropositivity and the subsequent onset of the disease, as it was perceived around 1985).

The plausibility concept provides criteria for classifying hazards. The KOURILSKY-VINEY report, for instance, beside proven risks, makes a distinction between three separate categories of plausible risks, for which specific recommendations are made:

- Type 1: Substantiated potential risks (high plausibility). These are risks that have not been empirically shown to exist but whose presence is strongly suspected, based on practical observations, empirical correlations and in-vitro experiments. In this instance, a majority of scientists are convinced that the risk exists. These are the types of risks that should be referred to decision-makers for implementation of the precautionary principle. The effect of humans on global warming or the human incidence of BSE are examples of this type.
- Type 2: Plausible potential risks (medium plausibility). Several facts and observations serve as a basis for assumptions that are considered valid by a substantial portion of the scientific community but still need to be confirmed or disproved by empirical observations or data. KOURILSKY and VINEY suggest that this type of situation arises whenever there is "a minority assumption based on a procedure considered valid by the majority". It is premature in this instance to alert decision-makers for the purpose of implementing the precautionary principle. However, it would be advisable to initiate specific research (if necessary with the support of decision-makers) in order to clarify the issues singled out. This is the category to which may belong the matter of possible changes in the nutritional properties of first-generation GM foods not detected by conventional toxicology and substantial equivalence tests.
- Type 3: Speculative risks (low plausibility). These are "purely speculative" risks on which working hypotheses in certain research laboratories are based, but for which no supporting factual data has been found. A discussion of these assumed risks should be restricted to the scientific community, at least for as long as no concrete evidence increases the plausibility of such conjectures. Risks of this third type would include the speculation that the genes of certain transgenic animals are transferred to bacteria in their digestive tract.

Although fairly theoretical, this classification points to two categories of risks that should trigger measures by decision-makers, in addition to proven risks, either in the form of preventive measures or of research to find out more about a risk. Risk assessment now becomes a more complex task, as it entails evaluating the degree of plausibility, even if this does not require the same consensus of opinion as in the case of proven risks. It is highly advisable here to allow all parties to express their views, so as to identify minority opinions and determine the status of risks (type 2 or type 3).

Evaluating Benefits: The Need for Social and Economic Appraisals

The addition of a cost/benefit analysis in connection with the implementation of the precautionary principle is sometimes considered part of the risk management process. If that is so, that analysis should be conducted by decision-makers. However, this view creates asymmetries between the assessment of risks, which is made by scientists, and the evaluation of benefits, which is entrusted to decision-makers. It is important, in my opinion, that any analysis of benefits be conducted by experts using the same methodology and working with the same degree of care as those evaluating risks, especially if the goal is to ensure that the cost/benefit analysis is not seen as a way to "compromise on risks". The qualifications of the experts would obviously have to be different and more specialists in

economics and social sciences will be required[7]. Obviously, the work of such experts would be restricted to evaluations and they would not replace decision-makers. They would make it possible, however, as in the case of risks, to make a distinction between proven, plausible and purely speculative benefits. In addition, their analysis would undoubtedly be contingent on a given social and economic system. It may therefore serve as grounds for trade restrictions, whenever the cost/benefit analysis results in approval being granted in one region and rejected in another. This is one more reason why it should be conducted scientifically and why international community must be able to verify its findings.

Monitoring Procedures: A Dimension of Assessment

Whenever a decision grounded in the precautionary principle satisfies the reversibility criterion and is based on data and assumptions that are still partly within the scope of scientific research, it is important that an effort be made to evolve toward a situation in which the risk will be either proven or ultimately disproved. That is why an effective monitoring system (traceability, biological monitoring) must be devised that provides for strong interaction between risk assessment and management. Risk assessors must decide what the relevant parameters are, how and with what frequency measurements are to be made, etc. based on what they believe is appropriate to ascertain the degree of plausibility of the risk. Decision-makers must suggest procedures that are adapted to the practical situation and available resources. This definition of an optimum system will probably require that scientists and decision-makers reach compromises. What matters most is that the system be designed as a part of the risk assessment procedure and not as the exclusive prerogative of decision makers, as this could hold true in the case of the monitoring of proven risks.

Conclusions

It is now evident that implementation of the precautionary principle has a considerable impact on this phase of risk assessment. It requires an expansion of the scope of evaluations and the development of multidisciplinary and adversarial procedures in order to identify both negative factors (risks) and positive elements (benefits), evaluate their plausibility and help design relevant monitoring measures.

We shall now examine the equally significant effect of the introduction of the precautionary principle on the participation of “civil society” in assessments.

The Precautionary Principle and Public Participation

How to Interpret the “Expert Assessment Crisis”

We have seen that the “standard” model for analyzing food safety considers the communication of risks as the third stage of the process, coming after the work of scientists and decision-makers. Its objective is to inform society of the work accomplished during the first two stages. Exchanges of an interactive nature are sometimes initiated, but scientists

[7] This is a separate issue from that of the participation of representatives of society at large referred to later. The point here concerns the inclusion of scientists from these branches, and just as a sociologist specialising in consumer behaviour is not a representative of consumers, an economist studying innovation cannot claim to speak on behalf of industrial firms.

and decision-makers retain full control over the work they do. The Codex Committee on General Principles defines communication on risk as "the interactive exchange of information and opinions concerning risk among people responsible for risk assessment and risk management, consumers and other interested parties.". The aim of disseminating information about a risk would hence be to reduce, after the fact, differences in perception by scientists, who have arrived at an accurate appraisal of the actual risk, and ordinary citizens who, lacking the necessary tools, may have a distorted view of the risk – a situation which needs to be corrected.

Food crises and the popular crisis of confidence concerning the risk assessment system have been seen in some quarters as a throwback to irrational attitudes, fed by more or less justified fears (fear of the changeover to the new millennium, a growing fear of change in affluent societies, etc.). This point of view would make it mandatory to improve risk communication, while keeping its "educational", terminal and downward nature unchanged, since its purpose is to allay irrational fears through the dissemination of objective scientific information.

Diametrically opposed to this view is the "social theory of risk" approach, developed in particular by Sheldon KRIMSKY, Paul SLOVIC and Claire MARRIS[8] over the past ten years or so, which focuses on the analysis of considerations that cause people to consider a risk either acceptable or unacceptable. It emphasizes the rational aspect of risk assessment by the population, while at the same time showing how that rational approach is not the same as the quantitative approach of the "standard" model.

People would seem to assess risk in an empirical manner that, on the whole, is quantitatively sound. There is a positive correlation between the actual number of deaths associated with a hazard and estimates made by "ordinary" citizens, even though they tend to overestimate low risks and understate the importance of high risks. Hence, it cannot be said that there is a lack of information about what assessment experts refer to as the "real" risk.

The popular classification of risks is based on a different assessment, however, whereby their "importance" is defined as a set of qualitative attributes (the risk "properties") rather than as a quantity. A total of 18 risk properties have thus been defined which, besides measuring the qualitative importance of a risk, determine its acceptability. Among these properties are:

- the risk's voluntary ("I decide to be exposed to the risk") or forced ("Someone else exposes me to it") nature;
- the risk's known ("I know when I am exposed to the risk") or unknown nature;
- the risk's immediate ("I am quickly aware of any effects") or deferred impact, with consequences for future generations considered an extreme instance of deferred impact;
- the risk's fairness ("Those responsible for the risk are those exposed to it") or unfairness;
- the risk's catastrophic potential, i.e. the number of persons concerned by the problem;
- the confidence or lack of confidence in the assessment of the risk by scientists.

People also automatically view risks from a cost/benefit standpoint, whenever they realize that a risk exists and therefore entails a potential cost. The evaluation of benefits is complex and involves considerations of an economic, cultural and psychological nature, which can

[8] See, especially: SLOVIC (1992) and MARRIS (1999).

vary considerably from one individual to the next. It is therefore understandable that people are somewhat reluctant to endorse the "standard" assessment by experts[9].

If one were now to examine, in that same light, health risks associated with food along with recent social trends in this sector, all factors that have gradually increased the distance separating consumers from food producers would have to be underscored. From a rural system in which food was produced, processed and consumed by family members, society has moved to an urban system, where food is processed industrially by firms scattered throughout the world. This has caused most risk attributes referred to earlier to become their own opposites. Whereas exposure to risk used to be voluntary, known, fair and with immediate and limited consequences in the traditional food system, food-related hazards are now unknown, imposed, unfair, with a deferred impact (risks from pesticides, heavy metals, etc.) and likely to affect a large number of people. This "catastrophic potential" is the result, in particular, of the concentration that has occurred at all levels of the food system, from production and processing to distribution and consumption – the latter due to the growing role of institutional catering, with a single food service company often running several employee restaurants.

Because of these changes in qualitative attributes, there has been a decline in the acceptability of risk, in spite of claims by experts that the numbers of people affected have gradually declined. This change can be exemplified by the case of botulism, a serious form of food poisoning caused by inadequate sterilization of tinned goods. The condition occurred relatively frequently in the past, when food was preserved at home, but has since declined significantly due to progress in industrial sterilization. Nevertheless, an application of the analysis above shows that "home" botulism used to be far more acceptable than its "industrial" equivalent.

This shows that the assessment of risk by the population is not irrational, but that it is based on a logic that is different from the rationality of experts, as it takes into account more diverse criteria and considerations regarding possible hazards and benefits. From this standpoint, it is not a matter of a rational group being in opposition to an irrational one, but rather of a conflict between two different types of rationality, which must be recognized and encouraged to interact in a synergistic manner during all stages of the analysis of risk. That is why the resulting qualitative and participatory model for the analysis of risk is said to be "constructivist", as opposed to the positivist and quantitative standard model.

How to Promote Interaction Between Experts and the Public at Large

Various types of structures have been suggested and sometimes developed in order to include the population in the analysis of risks. We have identified four main types, which we shall call here the "witness model", the "full membership model", the "judge model" and the "second circle model". Each deserves to be examined in depth, but we shall merely describe here their basic features and provide some indication as to how suitable they are to the goal of achieving genuine synergy between experts and ordinary citizens. Nor shall we discuss the complex issue of how citizens may be selected[10] and receive training if necessary, or the discussion and decision-making procedures within those structures.

[9] This real or perceived inequality in relation to risk is also one of the factors that accounts for resistance to probabilistic analysis, which often simply evaluates an average risk that is supposed to apply to the whole population.

[10] Procedures can also be designed to allow the entire population to express their views, as in the case of the recent vote on bio-engineering in Switzerland, but they are difficult to implement on a regular basis, even with the help of modern communication technology.

The witness model provides for only a limited role by the representatives of society at large. It suggests adding a small number of citizens to expert bodies for the purpose of attending discussions and verifying that they are properly conducted (to ensure that there is a full and thorough debate, that minority views are taken into account, that the findings are in keeping with the discussion, etc.). One possibility under this model would be to open meetings of expert bodies to the public, as in the case of parliamentary debates. This first option, under which the population is not involved in the actual assessment, is entirely compatible with the standard model. It makes it possible to communicate about the risk in real time (as opposed to after the fact), effectively improving the quality of information provided. It is most suitable in fields where the analysis of risk is an essentially technical task (such as, perhaps, in the medical field).

The second model makes representatives of society at large full members[11] of expert bodies. They may participate in discussions, present their opinions, including their opinion of qualitative aspects of the risk that they believe are important. They can also play an active role in drawing up the most exhaustive possible catalogue of hazards (see IV.1) by insisting that that phenomena be taken into consideration even if scientists do not necessarily consider them hazardous. For example, in the case of genetic engineering, expert bodies seem to have minimized the significance of the impact of GM crops on "non-targeted" plants and insects that are considered neither useful nor harmful. The issue was brought into public debate at a late stage. Similarly, in assessing economic and social costs and benefits (as discussed above), popular participation can help identify the qualitative and long-term issues involved (quality of life, ethical aspects) and extend assessments beyond purely quantitative notions, which are often of relatively short-term interest only.

This model of citizen-members describes the system created in 1992 in France for the assessment of genetic engineering. The bio-engineering commission (Commission du Génie Biomoléculaire – CGB[12]) includes several members at-large (representatives of consumers, environmental protection associations, members of parliament, etc.) with voting powers. The same model has been used in the case of risk management: the bio-monitoring committee originally formed to decide what measures should be taken to monitor the first commercial crops of genetically-modified maize includes several representatives at-large. In the United States, the charter of the FDA committees also provides for the inclusion of at least one member representing the consumers' point of view and recognizes the value of their participation by noting that contributions by consumer representatives are appreciated because they raise consumer issues which would otherwise not be considered before products are placed on the market (GUILLON, article in progress).

The third model provides for adversarial assessment procedures based on the legal system[13]. Experts are called upon to defend opposite points of view before a "jury" made up of representatives of the public at large. That jury is responsible for ultimately issuing findings regarding the assessment of the risk and any appropriate control measures. This practice has been tried out in Europe (including in Denmark and, more recently, Great Britain and France) through "consensus conferences" on genetic engineering. Although the method is useful in specific situations at the start or end of an important debate, it is probably difficult

[11] They may have either consultative status or the right to vote, but this issue will not be examined here.

[12] The commission examines all applications for the dissemination of GM substances for experimental purposes or for commercial distribution (micro-organisms, plants and animals for use in agriculture, food processing, the biomedical field or environmental protection). It handles some fifty applications a year.

[13] Arguments in favour of this model are made in particular by P. ROQUEPLO (1997).

to implement in the case of on-going activities and would entail an increase in the "rigidity" of the assessors' task. Most scientists are not accustomed to making statements that are as clear-cut as those of prosecutors or lawyers. They prefer to present analyses that include both positive and negative observations before reaching their conclusions. In addition, this approach keeps citizens at a relative distance from the assessment process, even if the jury can ask for a debate on issues it deems important. The experts are also in a delicate position. Because they are in some way being judged as a group, they may develop corporatist attitudes that are not compatible with an open and balanced discussion with representatives of society. In this regard, the citizen-judge model is perhaps closer to the standard model and to its communication concept than to the constructivist model.

The fourth, or second-circle model, is that suggested by, among others, the KOURILSKY-VINEY report. For fear that the presence of at-large representatives on committees of experts (as in the full-member model) should lead to misunderstandings and confusion as to the criteria used[14], it proposes to divide responsibility for the assessment between two separate groups (or circles):

- The first is that of scientific and technical experts working essentially in accordance with the standard model and measuring risks, but including among those risks the substantiated potential risks likely to require implementation of the precautionary principle.
- The second circle is made up of a group of representatives of society at large and reviews the findings of the first group. Its membership also includes economists and some representatives of the first circle. It is that second group that would examine possible benefits and hence the cost/benefit factor, as well as discuss various possible alternatives for applying the precautionary principle.

There would of course be some interaction between the two circles. The second could for instance refer certain issues back to the first for further study. The conclusions reached by both circles, whether consistent or conflicting, would be forwarded to decision-makers. This formal framework for the debate between experts and society at large has the advantage of clearly defining their respective roles. On an international level, it also provides an incentive for the reciprocal recognition of analyses conducted within the first circle, which would have a similar structure in all countries. Nevertheless, because of its rigid nature and the inevitable effects of group identification, it could slow down progress toward a genuine "common culture" in regard to risk assessment. The model can also frequently generate contradictory signals, leading to a certain perplexity in the minds of the public and some suspicion that final decisions may be arbitrary, regardless of their nature (unless one of the two circles is given final say, as in parliamentary systems). Hence, theoretical gains associated with the model in terms of credibility and clarity, as compared with the full-member model, may be almost fully cancelled out in certain circumstances. To our knowledge, the model has not been tested in practice. It deserves to be tried out in certain situations so that a clearer picture of its benefits and limitations may emerge.

Conclusion

We have described and compared, in a necessarily simplified manner, two extreme models for analyzing risk, namely the so-called "standard" model, based essentially on experts and

[14] "The separation of the two circles reflects the fact that there are two distinct categories of assessment imperatives involving different sets of participants. It has frequently been remarked that merging them was detrimental to the achievement of the objectives sought." (Report, page 41).

the prevention of proven risks, and the so-called "constructivist" model, which implies participation by society at large as well as the implementation of a precautionary principle proportionate to plausible risks. Three observations are in order to complete this presentation:

- First of all, in terms of the objective identified in the introduction, it is clear that any comparison between the models must consider the extent to which they achieve that final objective, instead of focussing on individual phases. It serves no purpose to have the best risk assessment system, or the best management, or even the best communication if a weak link undermines the final result.
- In regard to that final objective, we have focused mainly on the situation where the experts do not appear to have paid enough attention to risks perceived by the population. The models must also be considered in terms of the opposite situation, namely in the event that experts identify a risk which they deem important but which public opinion disregards or minimizes. For example, the increase in infantile obesity in industrialized countries is considered by experts to be a major medium-term public health problem but seems to be ignored by the public. A constructivist model can contribute to raising the public's awareness of such issues at an earlier stage.
- Lastly, if systems for analyzing risks, which affect an important aspect of people's lives, must be endorsed and trusted by the public, they must also take into account the specific social and cultural situations of countries or groups of countries. They should therefore use the models and principles described here as examples, to a varying extent. Let us hope that their diversity, which reflects the infinite variety of human societies, will be seen as a source of progress and shared experience, rather than as unwanted diversity, inherited from the past, which must gradually be eliminated.

References

BERGER et al., 1999. New England J. of Medicine, 341, pp. 1557-1564.

GRAHAM, J.D., 2000. Decision-Analytic Refinements of the Precautionary Principle. J. of Risk Research (in press).

GUILLON, F., (article in progress). Gestion des risques et des crises alimentaires.

KOURILSKY, P. and VINEY, G., 1999. The Precautionary Principle. A report to the Prime Minister of France.

LATOUR, B., 1994. Risques collectifs et situation de crise. A Centre national de recherche scientifique (CNRS) seminar. CNRS Editions, Paris.

MARRIS, C., 1999. OGM: Comment analyser les risques ? Biofutur, 195, pp. 44-47.

ROQUEPLO; P., 1997. Entre savoir et décision, l'expertise scientifique. Sciences en question collection, INRA Editions, Paris.

SLOVIC, P. , 1992. Perception of Risk: Reflections on the Psychometric Paradigm. *In* Social Theories of Risk, S. KRIMSKY and O. GOLDING (eds), Praeger, Westport, Connecticut, pp. 117-152.