# « Approaches of risk: an introduction »

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# I. CLASSICAL RISK MANAGEMENT

## 1.1. GENERAL INTRODUCTION

Before tackling the issue of technological risks with a special attention to biotechnology, it must be recalled that while technological breakthroughs generate new risks and benefits, benefits have been until then unevenly distributed, concentrating mainly in industrialised countries. Thus, technological breakthroughs accomplished in the fields of agriculture, medicine and public health have contributed to attain in these countries standards of living as well as material comfort and life expectancy levels never reached before. In this part of the world, the impacts of earthquakes, the occurrence of famines and epidemics have progressively faded away, with the consequences that people live statistically longer and in better material conditions. The comparison with the situation prevailing in the developing world, where basic needs are far from being satisfied, is striking. Many people still have no access to water, drugs or education, according to the 2001 Report of the United Nations Development Programme[1]. Moreover, the income gap between the richest and the poorest is increasing as a result of globalisation[2].

We will start our analysis with a typical situation of industrialised countries. Notwithstanding their increased level of material security, people show a lesser tolerance to risks than before. It is as if human life had become a capital which must be preserved from any hazards, be they natural or the result of human activities. Therefore, the first question we propose to answer in this introduction is the following: Are we facing a *paradox* or simply a *greater sensitivity to risks* in these societies?

[1] For example, at the end of 2000 about 36 million people were living with HIV/AIDS, 95% of them in developing countries and 70% in Sub-Saharan Africa. More than 5 million became newly infected in 1999 alone. United Nations Development Programme (UNDP), " Making New Technologies Work for Human Development", New York, United Nations, 2001, p.13. Report webplaced: http://hdr.undp.org/reports/global/2001/en/

[2] The income gap between the fifth of the world's people living in the richest countries and the fifth in the poorest was 74 to 1 in 1997, up from 60 to 1 in 1990 and 30 to 1 in 1960. United Nations Development Programme (UNDP), "Globalisation with a Human Face", New York, United Nations, 1999, p.3. Report webplaced: http://hdr.undp.org/reports/global/1999/en/

Industrial societies have reduced certain risks but in the same time new technologies have generated uncertainties and *new risks* have emerged with the following characteristics:

- They put into question the traditional procedures of expertise and decision: important uncertainties remain in their assessment, and classical expertise is insufficient to define appropriate preventive measures;
- These remaining scientific and socio-economic uncertainties are calling for an increased participation of citizens and stakeholders.

Indeed, the widespread use of the category of risk throughout society and in daily life reflects its importance in the rationalisation process of modern times. *A new sensitivity to risk* has appeared as a result of the rise of material comfort and individualism in western societies. In the mass consumption society, the social solidarity of class and the sense of belonging to a community are losing ground, while new social movements and networks of actors are emerging. The mobilisation of the civil society and more particularly the rise of environmental concerns are putting into question the political authority. The faith in progress that has dominated western societies until recently has rendered, in the eyes of the public, the state responsible of the containment of risks. But this task is ever more difficult to perform as the economic sphere is getting more autonomous and influent as a result of globalisation. And the nation-state has become too small to manage technological risks, since they often have cross-border effects.

In this context, the principles of classical risk management fail to address and prevent new risks. Controversies and political crisis have occurred more than ever with regard to the acceptability of risk, transforming the traditional public sphere and the modes of political decision. Since scientific and technical expertise is confronted to uncertainty[3] in a growing number of cases, the classical division of labour between expertise and decision, in other words between risk assessment and management, is put into question. The relationship between experts and lay people (i.e. people who have no specific scientific expertise), experts and users of technology, experts and citizens are in a process of transformation. New institutional settings and modes of risk assessment - like the precautionary approach - have to be implemented to respond to the demand of increased consultation on behalf of citizens and of increased participation of stakeholders and users of technology in decision-making.

[3] In our analysis, this term will have two meanings: used in the singular, it means scientific uncertainty. Used in the plural, it has a broader meaning, encompassing the social, political and economical uncertainties generated by scientific uncertainty (in other words, its secondary effects).

Among these new risks, one finds[4]:

- *Major technological risks*. They are generated by industrial complex and their damage is close to those generated by natural risks. They encompass chemical hazards like Seveso in Italy, Bhopal in India or atomic hazards like Tchernobyl in Ukrainia, and to a lesser extent Three Mile Island in the United States.
- *Food and sanitary risks*. They are resulting from the interplay of the market and technologies: for instance the food contaminated by the bovine spongiform encephalopathy (BSE or "mad cow disease") resulting in the development of the variant Creutzfeld-Jakob disease in humans and the contamination to HIV/AIDS in the contaminated blood crisis.
- *Environmental risks*. They stem from mass consumption and the consequences of industrialisation on the climate, the ozone layer, the quality of water, the accumulation of pollutants in the ground. One of their characteristics is to be global in scope: the climate warming or the depletion of the ozone layer have effects that concern the whole planet. People and states are more than ever interdependent from each other, since their behaviours have an impact on others in proportions never reached before.

It must be pointed out that these risks may affect the representations that Man has from himself, from nature, from life and death or God, and that stem from the technical possibilities offered by the mix of information communication technologies (ICTs), nanotechnologies and genetics. For instance, people engaged in the controversies on the development of genetically modified organisms (GMOs) or on the human cloning often emphasize the "ethical and philosophical stake" of these technologies.

Besides, these new risks have an endogenous character, either because the functioning of modern societies (institutional, economical logics) amplifies them or because they are directly the result of human activities (e.g. biotechnology)[5]. In this latter case, they are generally attributable to a human responsibility, which means that, when they materialise, it is always possible to say that someone could have avoided them. As shown by a Report by the European Environment Agency, the management of the mad cow disease crisis in Great Britain was handicapped by an institutional factor[6]. The department responsible for dealing with BSE was the Ministry of Agriculture,

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[4] This classification is partly taken from Bourg D. and Schlegel J.L. in " Parer aux risques de demain : le principe de précaution ", Paris, Seuil, 2001, p.45.

[5] Based on Gilbert C., " La fin des risques ? ", *Quaderni*, vol. 48, automne 2002, p.113.

[6] European Environment Agency (EEA), " Late Lessons from Early Warnings : the precautionary principle 1896-2000", Copenhagen, Environmental issue report, n°22, p.157. Report webplaced:
http://reports.eea.eu.int/environmental_issue_report_2001_22/en/tab_content_RLR

Fisheries and Food (MAFF), and it was expected simultaneously to promote the economic interests of farmers and the food industry, whilst also protecting public health from food-borne hazards.

To answer our introductory question, we can say that the combination of these two factors, the emergence of *new technological risks* on the one side, and of a *new sensitivity towards risks* on the other, makes the aforementioned paradox only apparent. In the next chapters, we are going to expose the classical risk management procedures, before tackling more controversial issues such as the precautionary approach and the negotiation of the acceptability of risks.

## 1.2. INTRODUCTION TO CLASSICAL RISK MANAGEMENT

As defined by probabilistic approach, risk is a well identified danger whose occurrence can be adequately expressed as probabilities. Mathematically expressed, risk (R) is the damage (D) multiplied by its probability (P):

$$\mathbf{R = D * P}$$

When this risk parameter is small enough, either in its probability of occurrence, or in the gravity of the damage, it is considered to be negligible. This is usually determined arbitrarily without social debate, and is referred to as "residual risk".

The notion of risk has been framed by the insurance sector as a tool to reduce uncertainties in order to calculate premiums. In this perspective, it is calculated in monetary terms by multiplying the damage by its probability. Alongside the development of the welfare state, the 20th century has seen the extension of the number of dangers that could be characterised as risks and consequently be assured[7]. Risk, then, became the tool used by experts in charge of risk assessments.

We will first review the classical classification of risks, before analysing the procedures used to assess and manage them.

[7] Peretti-Watel P. " La société du risque ", Paris, La Découverte, 2001, p. 14.

## 1.3. KNOWN AND HYPOTHETICAL RISKS

Usually a schematic distinction is made between two categories of risks, "known risks" on the one hand and "hypothetical risks" on the other, to which correspond two different public policies.

When the relation between a cause and an effect is established, we talk of *known risks*. The responsibility of such risk can generally be attributed. This category encompasses two situations, one where the probability of occurrence of the danger can be empirically assigned by statistics or other means. This category is the one that is best managed by insurance agents, since it fits the probabilistic approach. It can be illustrated by car insurance where probabilities to determine the risks of accident are based on statistics taking into account the age as well as the past behaviour of the driver. The second situation is the one where the probability cannot be empirically determined. It can only be assigned on the basis of the actors' rational arguments, convictions, feelings and intuitions. Anti-seismic insurance for buildings in countries subject to earthquakes such as Japan, Turkey or the USA are good illustrations of this category. In this case, the lack of data prevents the empirical determination of the probability of occurrence.

In both situations, the causal relation being established, prevention can be applied.

As for *hypothetical risks,* the relation between a cause and a damage is not well established. We have a "risk of risk", since neither the existence of the danger and the importance of the damage, nor its probability are known, both being still in the realm of hypotheses. This situation is best characterised by a general *state of suspicion* in which people gather indications and hypotheses on dangers that are not yet objectively established[8]. On that basis, *early warnings* can be activated by "whistle blowers", i.e. people (whatever their status) who give the alarm. In making public these information, whistle blowers may open the way to the unfolding of a *controversy*, where hypotheses on causal relationships are discussed among experts and scientists[9]. This process may eventually lead to the reduction of the level of uncertainty and the transformation of hypothetical risks into known risks. Where hypothetical risks prevail, it is generally admitted that a "precautionary approach" can be applied. The controversy concerning mobile phones constitutes a good example of hypothetical risks, that is to say the effect of the radiation produced by the phone on the head of users and of the relay

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[8] Callon M., Lascoumes P., Barthe Y., " Agir dans un monde incertain : essai sur la démocratie technique ", Seuil, Paris, 2001, p. 42.

[9] Chateauraynaud F., Torny D., " Les sombres précurseurs : une sociologie pragmatique de l'alerte et du risque ", Paris, éd. de l'Ecole des hautes Etudes en sciences sociales, 1999, p. 80.

antennas on people living in their vicinity. Indeed, the physiological impacts of this high-frequency radiation is considered as almost non-existent by experts as far as relay antennas are concerned. Concerning the mobile phone itself, a level of scientific uncertainty is acknowledged and precautionary measures like the use of a headphone is sometimes recommended.

The case of the mad cow disease (hereafter depicted) is a good example to illustrate how different elements have been successively shaped into different degrees of proof; uncertainty areas have been in part lighted up, and from mere suspicion we eventually came out with univocal evidence. Indeed, reality offers generally a subtle and complex mix of clues, signs, information, correlation and partial proofs that cannot easily be fitted into the somehow artificial model according to which there should be a clear line of demarcation between precaution and prevention. The main scientific developments of the mad cow disease are described in this box. The corresponding degree of proof is given for each stage, so as to illustrate how uncertainty has been progressively reduced with the advancements of scientific research.

| ***The story*** | ***The degree of proof*** |
|---|---|
| Scrapie is a transmissible spongiform encephalopathy (TSE) endemic in sheep and goat populations. It was known in Europe since mid-1800s (Brown and Bradley, 1998) and nowadays it has spread in many countries and is particularly frequent in the United Kingdom (UK). Scrapie is not transmissible to humans.<br>Since the beginning of the 20th century, animal carcasses have been recycled into animal feed. The increased risk of disease transmission that this practice involves induced the United State Department of Agriculture to ban sheep and goat afflicted with scrapie from being used in human or animal food since mid-1970s. In the UK, this practice was only stopped in 1988. | |
| In 1986, the first cases of bovine afflicted with an unknown TSE form that resembled scrapie were reported in the UK. This new disease was later called bovine spongiform encephalopathy (BSE). Like scrapie, it was caused by an unconventional infectious agent, the prion protein (PrP) and it had invariably a fatal issue. In the following years, other animals like domestic cats - that are not susceptible to scrapie - were afflicted with a similar TSE (Jeffrey et Wells, 1988; Fleetwood et Furley, 1990; Wyatt *et al.*, 1990; Kirkwood *et al.*, 1990; Willoughby *et al.*, 1992). Those animals had been fed with meat and bone meal or uncooked tissues including cattle heads and spines. | *There is suspicion BSE might be responsible for the TSE cases in domestic cats. As cats are not susceptible to scrapie, this would mean that BSE has a different host-range than scrapie and that it might therefore also contaminate humans.* |

| ***The story (following)*** | ***The degree of proof*** |
|---|---|
| In 1994, before first cases of variant Creutzfeld Jacob Diseases (vCJD), laboratory experiments showed that the BSE prion induces a disease in mice with particular characteristics in term of incubation period and neuropathology, that were identified as the BSE "signature". The mice developed the disease even if, before transmission, the prion had passed through different species (Bruce *et al.*, 1994). The infectious agent responsible for the new cat TSE was also tested on mice which developed a similar disease with the BSE "signature" (Fraser *et al.,* 1994). | *These results confirmed the suspicion, even if indirectly, that BSE had been transmitted to cats and is therefore able to cross species barrier in cases where scrapie was not.* |
| In 1996, ten years after the first cases of BSE, a new form of Creutzfeld Jakob Disease (CJD) appeared in the United Kingdom. It affected younger patients and had very different neuropathological features than sporadic CJD. Most cases of this vCJD have been reported in areas where the BSE epidemic was present, that is to say mainly in the UK. Furthermore, the cases of persons with vCJD reported outside of England had all a history of stay in the United Kingdom since 1986 or at least in one of the other European countries affected with BSE. | *There is a clear geographical correlation between the regions affected with BSE and those affected with vCJD. A temporal link can also be established between the two diseases inasmuch as the long incubation time of most TSE could coincide with the ten years delay between first BSE cases and the apparition of vCJD. Furthermore, vCJD was a totally new TSE, never recorded before 1996.* |
| The same year, biochemical analysis revealed that the prion protein (PrP) involved in vCJD resembled the BSE one while differing from that of sporadic CJD (Collinge *et al.*, 1996). Later, the analyse of mice contaminated with sporadic CJD and vCJD prions showed that the disease induced by the vCJD harboured the BSE "signature" whereas those contaminated with sporadic CJD had a different disease pattern (Bruce *et al.*, 1997). Furthermore, BSE prions and vCJD prions gave a similar banding pattern on western blot analysis (Scott *et al*. 1999). | *These results brought strong evidence that the same prion strain is involved in both BSE and vCJD and therefore that BSE prion is the agent responsible for vCJD.* |

| ***The story (following)*** | ***The degree of proof*** |
|---|---|
| The human genotype at polymorphic codon 129 of the prion protein gene (PRNP) appears to play an important role in susceptibility to infection. All the vCJD-affected patients tested for this polymorphism were homozygous for methionie (methionine/methionine) at codon 129 and it seems that the BSE prion is not able to replicate in other gentoypes (for example methionine/valine or valine/valine). But it is possible that people with the heterozygous genotype Methionine/Valine are more resistant to the disease and become ill only after longer incubation periods than those with the Methionine/Methionine genotype. (Cervenáková *et al.*, 1998; d'Aignaux *et al.,* 1999; Brown *et al.*, 2000) | *There is strong epidemiological evidence that susceptibility to vCJD is determined genetically.* |
| However, recent data (Asante *et al.*, 2002) showed that transgenic mice with the 129-met human prion gene developed both the vCJD and the sporadic CJD when contaminated with either BSE or vCJD prions. | *These results indicate that the BSE agent might be responsible not only for vCJD, but also for sporadic CJD in patients homozygous methionine/methionin e at codon 129 in the prion gene.* |
| Regarding the localisation of the infectious agent, it has been shown that nervous tissue (brain, spine cord, peripheral nerves) as well as lympho nodes do contain the BSE prion. However, it is still not clear whether muscle is infectious as it has never been reproducibly shown that it contained the infectious agent, neither in BSE nor in other TSE. Still, the contamination might result from beef products contaminated by nervous system tissues during slaughter, or in the "mechanically recovered meat" on the carcasses that is then used in some meat products such as meat pies, beef sausages or canned meat preparations. | *Normally, beef muscle should be safe, but this assertion does not take into account possible contamination due to mispractice or accident.* |
| At the moment, there is great concern about the possibility BSE has been transmitted back to sheep, and whether these sheep might be infectious for humans. Laboratory experiments have shown BSE can transmit to sheep by the oral route and that a dose as little as 0.5 BSE-affected bovine brain can transmit (Foster *et al.*, 1993). There is no quick and reliable technique to detect BSE in sheep and to distinguish it from scrapie. The only method available relies on mice testing to see if they develop disease with the BSE "signature". But even that technique would not be reliable to detect sheep-adapted strain of BSE, which might have lost the distinguishing characteristic found on primary passage from cow to sheep. Furthermore, if sheep BSE can transmit horizontally (from one animal to another) or maternally (from mother to son), like scrapie, there might be a sheep BSE going on, but not distinguishable from scrapie. | *BSE was able to cross the species barrier, it is possible it also crossed the barrier back from cow to sheep. The absence of technical mean to reliably distinguish scrapie from a possible sheep BSE as well as the uncertainty regarding the host-range of this possible disease means that a the risk for humans cannot be excluded.* |

To conclude, we see from this short and selective description of the BSE crisis that many questions have not yet found an answer. For example, the origin of BSE (from scrapie or not), the threshold level of infectivity, the exact nature of the prion, its remanence in the environment, the incubation time of the disease, the number of persons affected, the possible cross back of BSE to sheep, and s.o. still remain uncertain.

Do we therefore still face hypothetical risk? Regarding the fundamental question about BSE - namely whether the BSE prion is able to cross species barrier, to contaminate humans and to cause the vCJD - this is already clear. Indeed, even if the direct observation of the passage of the BSE agent from cow infected tissues to humans and the subsequent development of the vCJD has not been possible for practical reasons, the gathering of diverse partial proofs brought strong evidence. It can therefore be said that from 1996 to 1999, we progressively left the regime of precaution to enter the regime of prevention.

It is interesting to note that the irony of the BSE story is that while it should now come to an end, it is in fact as if it were starting again. The fact the BSE prion might have crossed back to sheep means indeed that the precautionary approach should be applied once again, until answers to the following questions will have been found: "Has the BSE prion crossed back to sheep and are these BSE infected sheep infectious for humans ? ". But that is another story.

## 1.4. RISK ASSESSMENT AND MANAGEMENT

It is generally believed that risk assessment and management are procedures that can be performed separately. This is the reason why we present them in their chronological order of appearance, before addressing the pros and cons of such a separation. But first, it is important to make some terminological remarks. " Risk management " is an ambiguous term, since it has a specific as well as a generic meaning. Indeed, it is either the procedure following the risk assessment or the general process that includes both the assessment and management of risks. We will use (in fact we have already used) these two meanings depending on the context. In addition, it must be noted that when international organisations such as the UN Food and Agriculture Organization (FAO), the World Health Organization (WHO) or the Codex Alimentarius Commission refer to its generic meaning, i.e. the risk assessment and management procedures, they have recourse to the term "risk analysis"[10].

Risk assessments are traditionally performed by scientific experts. It is made of four steps[11]:

1. **Hazard identification**: the identification of biological, chemical and physical agents capable of causing adverse effects on human health (cancers, allergies, genetic harm) or the environment (reduction of biodiversity, eutrophy). For example, nitrates and nitrites coming from washing powders and fertilisers have well known effects. Nitrates have a negative impact on the environment for example by inducing the proliferation of algae in lakes and rivers. Nitrites can induce cancers in the gastrointestinal tract when transformed in substances called nitrosamines.
2. **Hazard characterisation**: the qualitative or quantitative evaluation of the nature of the adverse health or environmental effects. Ideally, a precise evaluation of the relation between the quantity of the substance and its effects is determined (dose/response relation) like in the typical case of drug trials. Epidemiology is used to assess the impact on large populations and toxicological testes are performed on animals. This stage of the process is quite abstract in nature and often removed from the complexity of real exposition conditions.

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[10] For example, a more detailed description of what is meant by " risk analysis " for the Codex Alimentarius Commission is given at the following address : http://www.codexalimentarius.net/biotech/en/ra_fbt.htm

[11] Based on De Sadeleer N., Noiville C., "La gestion des risques écologiques et sanitaires à l'épreuve des chiffres : Le droit entre enjeux scientifiques et politiques ", *Revue de droit de l'Union Européenne*, 02/2001, pp. 398-99; Hathaway S., " Risk Analysis in Biosecurity for Food and Agriculture ", pp. 8-9.

3. **Exposure assessment**: the qualitative or quantitative evaluation of the likely intake of food-borne hazards and how the diverse components of environment will be exposed to the effects of the substance, taking into account other exposure pathways where relevant. This stage is more complex because it must evaluate the exposition in everyday life conditions, i.e. outside the laboratory. The exposition and transmission pathways, the categories of population or the compartments of the ecosystem which are affected must be identified. Exposure is dependent on geographical and cultural parameters like food traditions, medical practices, etc. For instance, in the case of nitrites, an evaluation is made of the amount of fertilisers used in the fields as well as of the percolation processes which induce the contamination of the phreatic water used for consumption. Parents are taught not using drinking water for feeding new born children.
4. **Risk characterisation**: the qualitative or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse effects and damages. It tries to calculate for example the number of cancers induced by the absorption of nitrites in a given area by a given sub-population.

The number of sectors where the recourse to scientific expertise is mandatory before taking a decision is increasing[12]. For instance ecological and sanitary risks must be assessed before the commercialisation of new drugs or pesticides. The origin of this development is twofold. It stems first from the will to learn from past mistakes. In the aftermath of sanitary hazards which were the result of too empirical policies of products commercialisation, the idea is to avoid the release of products that would turn out to be dangerous after their commercialisation by better predicting their eventual negative secondary effects[13]. For instance "thalidomide" which was a drug marketed in 1957 to prevent morning sickness on pregnant women resulted in horrific birth defects in thousands of children around the world, before being banned by the early 1960ies[14]. This development also stems from the idea that science is the only "objective" mean to regulate risks, especially in the area of international trade. States willing to restrict free trade by prohibiting the imports of a given product have therefore to justify their decisions on a risk assessment. For instance, article 15 of the Cartagena Protocol authorises import restriction of certain "living modified organisms" (LMOs)[15] on the basis

[12] De Sadeleer N., Noiville C., *op. cit*., pp. 394-95.

[13] *Ibidem*, pp. 394-95.

[14] United Nations Development Programme (UNDP), *op. cit*., 2001, p.65.

[15] According to article 4, the Protocol does only apply to living modified organisms. By-products which contain no LMOs such as food are therefore excluded from its scope of application. For example, while a grain of wheat is a living modified organism, it enters into the category of "genetically modified organisms" as soon as it is transformed industrially into wheat mill. Pythoud F., " Le protocole de Cartagena sur la prévention des risques

of a risk assessment carried out by the state of import in a *scientifically sound manner*, i.e. in a manner that would demonstrate their potentially adverse effects on the conservation and sustainable use of biological diversity or human health in the receiving environment[16].

Here are the main steps set by the Cartagena Protocol for assessing biosafety risks. It must be pointed out that the scope of the assessment concerns the adverse effects of LMOs on the conservation and sustainable use of biological diversity, taking into account risks to human health. Besides, risk assessments should be carried out on a case-by-case basis[17]:

1. Identify novel LMO genotypic or phenotypic characteristics that may cause adverse effects;
2. Evaluate the likelihood of these effects being realised, taking into account the level and kind of exposure of the likely potential receiving environment;
3. Evaluate the consequences should these adverse effects be realised;
4. Estimate the overall risk based on likelihood and consequence;
5. Recommend as to whether or not the risks are acceptable or manageable, including where necessary, identification of strategies to manage these risks;
6. Where there is uncertainty regarding the level of risk, consider the need for further information, or implement risk management strategies and/or monitoring in the receiving environment.

Thus, risks assessments are at the heart of contemporary approaches to many sectors. In the field of biosafety, international organisations involved with human, animal and plant health, and biodiversity such as the World Trade Organization (WTO), the Food and Agriculture Organization (FAO), the World Health Organization (WHO) and the Organisation for Economic Cooperation and Development (OECD) have embraced risk assessment as an essential tool to achieve their goals. Therefore, provisions presenting principles and guidelines for application of risk assessment are incorporated in instruments such as the Codex Alimentarius Commission, the "Office International des Epizooties", the International Plant Protection Convention, or the already mentioned Cartagena Protocol[18].

Generally, *risk management* is presented as taking place after the assessment. It consists in the adoption of legislative or regulation measures related to the risk that has been evaluated and refers more fundamentally to

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biotechnologiques : Les enjeux principaux des négociations ", *Revue suisse de droit international et européen*, 10e année, vol.4/2000, p. 530.

[16] Cullet Ph., " The biosafety protocol : an introduction ", RIBios, 2002, p. 3.

[17] Hathaway S., *op. cit.*, p. 24.

[18] Hathaway S., *op. cit.*, pp.1-2.

the determination of an acceptable level of risk based on the risk assessment[19]. It is made on the assumption that "zero risk" is not achievable.

## 1.5. PROS AND CONS OF THE SEPARATION BETWEEN ASSESSMENT AND MANAGEMENT

This section, which reviews the pros and cons of the separation between assessment and management, is based on Noiville and de Sadeleer's juridical analysis of the management of ecological and sanitary risks[20].

According to these scholars, this separation is beneficial on two aspects:

- First and foremost, it has been designed to guarantee that any decisions be preceded by a scientific assessment, since decision-makers are not scientists. By providing a rigorous scientific background to decisions, this separation therefore aims at preventing arbitrary decisions.
- Second, this separation aims at guaranteeing the autonomy of public authorities and the separation of powers and competencies. If it is up to experts to make the scientific work of assessment, politicians or people working in administrative bodies have to adopt and elaborate measures. The results of assessments, while constituting a necessary basis of the decision, are in no way a substitute to political decisions. The conclusions of the assessment do not constitute an end in itself but only a tool for the decision.

According to Noiville and de Sadeleer, this separation has three disadvantages:

- First, it is too theoretical. In practice these two operations do not follow chronologically each others, but are overlapping each others. This is especially true in the context of a crisis when by definition time is lacking to make a precise risk assessment before adopting the adequate measures.
- Second, this separation takes for granted that it is possible to draw a distinct line between facts on one side, and values on the other; in other words between what is objective and what is subjective, between the questionable and the not questionable. The assessment would therefore rely on objective facts, while the management would be in the sphere of value judgements. Such a dichotomy is too simplistic. In reality, assessing

[19] De Sadeleer N., Noiville C., *op.cit*., pp. 400-01.

[20] *Ibidem*, pp. 406-16.

risks is an action that requires values, since experts have to make choices which, as any choices, can be biased by prejudices.

- Third, this separation could make these two steps autonomous from each others by submitting the management of risk to the results of the assessment. In this case, political decisions are reduced to be mechanically dictated by the expertise.

# II. PRECAUTIONARY PRINCIPLE

## 2.1. THE PRECAUTIONARY APPROACH IN INTERNATIONAL LAW

Since the precautionary principle is the object of many different formulations, one should rather talk about an *approach* than a principle. Here are some of its many formulations in international treaties and agreements[21]:

**Montreal Protocol on Substances that Deplete the Ozone Layer** (1987): "Parties to this protocol… determined to protect the ozone layer by taking precautionary measures to control equitably total global emissions of substances that deplete it…"

**Third North Sea Conference** (1990): "The participants will continue to apply the precautionary principle, that is to take action to avoid potentially damaging impacts of substances that are persistent, toxic, and able to bioaccumulate even when there is no scientific evidence to prove a causal link between emissions and effects.**"**

**The Rio Declaration on Environment and Development** (1992): "In order to protect the environment the Precautionary approach shall be widely applied by states according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

**Framework Convention on Climate Change** (1992): "The Parties should take precautionary measures to anticipate, prevent or minimise the causes of climate change and mitigate its adverse effects. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing such measures, taking into account that policies and measures to deal with climate change should be cost-effective so as to ensure global benefits at the lowest possible cost."

**Treaty on European Union** (Maastricht Treaty, 1992): "Community policy on the environment…shall be based on the precautionary principle and on the principles that preventive actions should be taken, that the environmental damage should as a priority be rectified at source and that the polluter should pay."

**Cartagena Protocol on Biosafety** (2000): "In accordance with the precautionary approach the objective of this protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements."

[21] European Environment Agency (EEA), *op. cit*., p. 14.

To give a very general definition of this approach, it can be said that it aims at managing *hypothetical risks* in a context of scientific uncertainty. It should be applied when the impacts resulting from a given phenomenon, activity or product, that are suspected to cause serious or irreversible damage, while not yet scientifically proved, have been partly identified through the collect of data[22]. The idea that led to its adoption is that one should not wait until risks are known risks (in the meaning given *supra*) to take measures. As for its application, it is hotly debated in the public space. Broadly speaking, four interpretations can be identified:

- For **researchers**, the precautionary approach is pushing to action rather than inaction since it gives incentives to make further research to generate new knowledge and provide proofs on the harmlessness of the phenomenon, activity or product under discussion. Besides, decisions taken on its basis should be reviewable according to the results of the research undertaken.
- Conversely, the interpretation of **some environmentalist groups** makes it an "abstention principle". For them, when applying the precautionary approach, one should not hesitate taking radical measures such as the prohibition of a specific activity or the setting of very stringent thresholds. This is likely to result in the impossibility of doing research to produce the necessary knowledge to confirm or infirm the validity of the hypothetical risks in question.
- For actors in **the industrial sector**, this approach is usually seen as a brake to "scientific progress" and an interference from the free market forces.
- In **the media and the public sphere**, the precautionary approach is invoked about almost any technological issue and used as a rhetoric resource. This fuzzy character sometimes contributes to discredit the notion among experts.

It must be recalled that when the relation between the cause and the effect of a hypothetical risk is eventually established, we enter into the category of known risks, and decisions become a matter of prevention.

[22] Callon M., Lascoumes P., Barthe Y., *op. cit.*, p.289.

The precautionary approach is the subject of a range of formulations because it is used differently according to the technologies involved and the degree of precaution required by each situation[23]. Six elements can be listed as criteria allowing to distinguish between the soft and strong formulations (i.e. in favour of a strict) of the precautionary approach:

- **Consideration of benefits and risks in current technology**. Soft formulations guide regulatory action by considering not only the harmful risks of technological change but also the potential benefits, as well as the risks of technology that would be removed. Strong formulations, in contrast, often examine only the direct risks of the new technology.
- **Cost-effectiveness of prevention**. Soft formulations emphasize the need to balance the costs of preventing potential environmental harms associated with a new technology against the costs of those harms. Strong formulations often do not weight the costs of prevention.
- **Certainty of harm or certainty of safety**. Soft formulations state that the absence of certainty of harm does not prevent regulatory action. Strong formulations often require certainty of safety to avoid regulatory action, which in complex and dynamic systems is often impossible to achieve.
- **Burden of proof**. Soft formulations place the burden of proof on those who claim that harm will occur if a new technology is introduced. Strong formulations may shift the burden of proof to the producers and importers of a technology, requiring that they demonstrate its safety.
- **Optional or obligatory action**. Soft formulations permit regulators to take action, while strong formulations often require action.
- **Locus of decision-making**. Soft formulations place authority on regulators, while strong formulations may vest power in political leaders.

Though quite new, it is good to recall briefly the development of the precautionary approach. From German law where it was first formulated in the 1970ies as the "Vorsorgeprinzip" in the field of environment (the Clean Air Act of 1974), it has progressively penetrated international law[24]. It was

[23] United Nations Development Programme (UNDP), 2001, *op. cit*., p.70.

[24] It is even possible to trace the origin of this approach earlier in American law. While not explicitly formulated in terms of precaution, the so-called 1958 Delaney Clause by prohibiting food for human consumption that contains carcinogenic substances is an example of " precautionary prevention " in food safety. Taken from the European Environment Agency Report, *op. cit.* , pp. 12 and 149.

first incorporated in the field of environment, before being extended to food security and public health in the aftermath of the mad cow crisis[25].

The use of precautionary approaches to hazards began however well before the 1970ies, particularly in the field of public health. One early application was by Dr John Snow, who in 1854 recommended removing the handle from the Broad Street water pump in London in an attempt to stop the cholera epidemic that was ravaging the centre of the city. Some evidence for a correlation between the polluted water and cholera had been published five years earlier by Snow himself. This evidence, though not "proof beyond reasonable doubt", was proof enough for Snow to recommend the necessary public health action, where the likely costs of inaction would have been far greater than the possible cost of inaction[26, 27].

[25] Godard G., Henry C., Lagadec P., Michel-Kerjan E., " Traité des nouveaux risques ", Paris, Gallimard, 2002, pp. 72-78.

[26] European Environment Agency (EEA), *op. cit*., pp. 14-15.

[27] For a more detailed introduction to the precautionary principle, please read : Van Griethuysen P. (2004) «Principe de précaution: quelques éléments de base», Cahiers du RIBios n°4.

# III. QUESTIONING OF THE CLASSICAL MODEL OF RISK MANAGEMENT

The aim of this chapter is to move away from the classical definitions of risk to a more socially oriented one. Before that, we will try to show that the classical risk management model implicitly excludes lay people from its process by drawing a line between objective risks on the side of experts, and perception of risks on the side of the public.

## 3.1. MODELS OF "TECHNICAL DEMOCRACY"

The classical risk management model is rooted in the paradigm of the "Public Understanding of Science" which has been stated in the 1985 document of the Royal Society of the United Kingdom. In this approach, science is presented in the public sphere as a unified institution. A clear-cut limit between experts and lay people is established. Rationality is exclusively attributed to scientific knowledge, and other kinds of understanding are only subjective discourses and values. Science is considered as neutral knowledge. That is why it ignores social contexts and representations, and it denies other forms of rational thinking in risk management. This exclusive attribution of rationality to scientific knowledge is based on its reputation of reliability. Therefore, when a risk or a new technology comes in, obstacles and problems are found in the lack of understanding of science by the public. The aim of public policy in the management of risk is to re-establish trust by information and education.

This mechanism has been clearly described in several sociological studies on the public views on GMOs, for example in the "Public Perceptions of Agricultural Biotechnologies in Europe" research (PABE)[28]. It challenged the myth commonly expressed by stakeholders in the GMOs controversy, according to which a better understanding of genetics would result in the acceptation of the technology by their opponents[29]. It showed on the contrary that more knowledge about GMOs makes people more sceptical or polarised, not less.

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[28] Marris C., Wynne B., Simmons P., Weldon S., " Public Perceptions of Agricultural biotechnologies in Europe (PABE Final Report)", Commission of European Communities, Lancaster University, 2001, p. 78.

Report webplaced : http://www.lancs.ac.uk/depts/ieppp/pabe/docs.htm

[29] For instance, when Monsanto, the American biotechnological company, campaigned vigorously in Europe in favour of biotechnology, it was persuaded that diffusing more information would directly increase public trust in their products. As we know, this strategy turned out to be ineffective.

The public understanding of science approach assumes that scientific evidence should carry conviction in society as it ideally does in scientific research. In doing so, it forgets that in society at large science is not the only narrative carrying conviction (policy, law, economics are other narratives) nor the only one granted of rational thinking. In addition, reason cannot be kept separated from values but rather needs values in its foundations. To conclude, the classical risk management approach may give pre-eminence to the interests of the actors with the highest degree of inclusion in the issue, mainly scientific experts and politicians.

According to scholars, aside of the public understanding of science model, two other models of the relations of science and technology in democratic procedures exist, the "public debate model" and the "co-production of knowledge model":

- **The public debate approach**: in this model, controversy is not interpreted as a lack of trust on behalf of the public, but more likely as a normal process of debate about science and technology's consequences. In addition to the traditional institutions of the public sphere (Parliament, media, etc.), a whole range of policies have been developed to complement the debate and allow a bigger diversity of actors to express their concerns (for example focus groups, consensus conferences, technology assessment). In the model of the public debate, science is accountable, and more sensitive to social contexts. There is recognition that a risk of new technology can put into question the cultural or professional identity of social groups.
- **The co-production of knowledge approach**: as its name indicates, the aim of this model is to include lay people in the elaboration of the knowledge that concerns them. Knowledge from lay people is considered here as an essential element. In this perspective, it enlarges the public debate approach, where knowledge from lay people is only taken into account to enrich the official expertise. The dynamics of knowledge is seen as the result of a permanent tension between the production of standardised knowledge in laboratories on the one hand, and the production of a knowledge that takes into account the complexity of local and particular situations on the other hand. The French Muscular Dystrophy Association, an association composed of people affected by genetic diseases, is a good example of collaboration in the production of knowledge, where users of genetic knowledge became the partners of researchers. Patients and their families directly involved themselves in the collecting of DNA samples, in the setting of specialised medical consultations, and in the financing of laboratories. The Généthon laboratory, created on the initiative of the French Muscular Distrophy Association, produced genome maps that made the completion of the Human Genome Mapping Project possible. The French Muscular Distrophy Association constitutes therefore a good example of a

"competent user-partner in the field of science"[30]. The co-production of knowledge will be further discussed in the sections dedicated to "hybrid forums".

The table below is given as an indication. More information should be provided to make it an analytical tool, which is not our purpose here. It depicts the three approaches under four angles:

- The nature of the relation between science and society ;
- The aims they pursue;
- The way they conceive expertise;
- The objectives of public policies.

| | **Science-society relations** | **Aim** | **Conception of expertise** | **Objective of public policies** |
|---|---|---|---|---|
| **1. Public understanding of science** | Autonomy | Information and education of lay people | Separation between experts and lay people | Restoring trust and favoring acceptability |
| **2. Public debate** | Complementarity | Inclusion of contexts and implications | Reinforcement of representation of concerned groups | Public discussion and negotiation |
| **3. Co-production of knowledge** | Reciprocal dependence | Participation of concerned groups to the production of knowledge | Symmetrical repartition of the expertise between the actors | Production of socially robust knowledge |

[30] This example is taken from an analysis of knowledge co-production in the domain of genetic diseases and human genome research by Alain Kaufmann, " Mapping the Human Genome at Généthon Laboratory : the French Muscular Dystrophy Association and the Politics of the Gene ", in *The mapping Cultures of 20th Century Genetics*, H.J. Rheiberger and J.P. Gaudillière, London: Taylor and Francis, forthcoming 2003.

## 3.2. EXPERTS AND SOCIETY

Before moving to a new definition of risks, it is necessary to review the notion of expertise, since experts are at the core of the dominant model of risk assessment and management.

According to Roqueplo's analysis[31], expertise is at the interface between knowledge and decision-making. The role of the expert is to provide knowledge, not to decide. What transforms a scientific statement into scientific expertise is the fact that it is integrated into the dynamics of a decision-making process and that it is formulated at the request, and for people who are in charge of taking decisions. It is the context and not the content of the statement that makes it, either the expression of scientific knowledge, or the expression of expertise. Thus, the nature of a statement – for instance, *x* milligram of the substance *y* constitutes a lethal dose for a species - will not be the same whether it is formulated in a scientific conference (scientific statement) or in an administrative procedure in charge of enacting rules to protect endangered species (scientific expertise).

Besides, scientific expertise always goes beyond the knowledge on which it is based; in other words, there is "transgression" of this knowledge for several reasons:

- First, the scientist in charge of the expertise must answer to a question he has not chosen. This situation stands in sharp contrast with the conditions he is used to deal with in the realm of research, since a researcher is normally designing his own questions of research.
- Second, the scientist has to apply his knowledge to the complexity and uncertainty of a concrete situation (for example, the impact of a pollutant on an ecosystem). This situation differs a lot from the situation of confined research, i.e. research performed in laboratories. In this case, researchers are free to determine which parameters to retain for their experiments, while at the same time keeping control of the others. Thus, it can be argued that expertise consists in making *social* scientific knowledge: knowledge is extracted from the laboratory where it was formulated and elaborated to be confronted to the complexity and uncertainty of the social and natural (ecosystems) worlds. Besides, the expert's answer has to incorporate other bodies of knowledge than his own, since the complexity of the world calls in other pertinent fields of knowledge.

These are the reasons why experts are not delivering scientific knowledge *stricto sensu* but something that can be considered "a reasonable knowledge

[31] This section is taken mainly from: Roqueplo P., " Entre savoir et décision, l'expertise scientifique ", Paris, INRA, 1996, pp. 11-49.

as objectively elaborated as possible"[32]. It is, in other words, the expression of a thought, a conviction, an opinion that is going beyond the limits of science, while at the same time relying on it. This kind of extrapolation implies by definition the engagement of the values of the expert. Expertise is not as neutral as some might think but is oriented by society. Experts are actors who are mandated by other actors, most of the time politicians, to provide basis for setting values, threshold levels and acceptable risk levels.

To make it more inclusive and to move it out of its purely qualitative aspect, risk management must be re-defined as *a learning process*. In this perspective, risk is considered a hybrid of cognitive and social nature. It is subject to different attributions of meanings, which vary in values and rationales across different world views.

[32] *Ibidem*, p.40.

# IV. BEYOND THE RISK FRAMEWORK: "TECHNICAL DEMOCRACY" AND THE DECISION IN A CONTEXT OF UNCERTAINTY

## 4.1. INTRODUCTION

Two elements will allow us to enlarge the scope of our analysis.

First, studies on public perceptions of risks reveal that lay people perceive risks in a more complex way than usually thought. Studies on public perceptions of risks have shown that, when people define risk, they are not so much interested in their probabilities of occurrence but integrate qualitative criteria such as the nature of the risks at stake (local or global consequences, short term or long term effects - which means more than one generation), the people concerned, the circumstances surrounding the risk exposure (voluntary or involuntary character)[33]. In this perspective, one of the conclusions that came out of the already quoted study on the public views on GMOs, the PABE final report[34], was that risk was not the main concern of citizens in their perception of biotechnologies. They were rather approaching the issue under the angle of uncertainties and their management. Indeed, according to this study, citizen did not ask for "zero risk" or full certainty with respect to the impacts of GMOs and were well aware that daily activities of ordinary lives are associated with numerous risks and benefits which have to be balanced against one another. Moreover, they deemed it natural that science could never accurately predict all future impacts of a new technology. Rather, they felt strongly that inherent and unavoidable uncertainties should be acknowledged by expert institutions, and be taken into account in decision making. That was the refusal of these authorities to admit the existence of these uncertainties as well as the lack of transparency in the way decisions were taken that were found to be disconcerting and untrustworthy. They expressed the view that for instance more information should be given on how different interests, risks and benefits were balanced against one another in the decision-making process.

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[33] In fact, according to the "psychometrical paradigm", 18 characteristics can be identified in the process of risks evaluation (i.e. to decide if they are acceptable or not) when performed by lay people. Taken from Marris C., " Comment analyser les risques ? ", *Biofutur*, décembre 1999, n°195, pp.44-47.

[34] Marris C., Wynne B., Simmons P., Weldon S., *op. cit*. (PABE Final Report), p. 60.

Second, the classical risk management model is applicable to technologies that generate known risks, i.e. where the relation between a cause and an effect is established. It is hardly applicable to technologies generating hypothetical risks.

Indeed, these technologies give rise to dangers that may have the following characteristics[35]:

- their causes are not precisely identified, and thus are the subject of controversies among experts and scientists.
- their consequences are difficult to estimate, and sometimes not even clearly linked to defined causes.
- it is not possible to attribute them probabilities of occurrence.

In other words, new technologies such as GMOs or mobile phones bring in uncertainties that cannot be reduced by the classical risk management procedures. These procedures find therefore their limits when they are confronted to the category of hypothetical risks. New designs, such as the precautionary approach, have to be elaborated in the decision-making process to improve "technical democracy". It means procedures that will allow to go beyond the double delegation on which the classical model is based, i.e. the delegation from lay people to experts in the risk assessment and the delegation from citizen to their representatives in the risk management are needed. This is the issue that is addressed in the next sections.

## 4.2. THE DYNAMICS OF CONTROVERSIES

We shall start our exploration of technical democracy by defining the concepts of "socio-technical controversies" and "hybrid forums"[36].

In a context of scientific uncertainty, scientists and experts are in a state of near ignorance[37]. They are arguing about which hypotheses have to be taken into account to explain what is not yet explainable. This situation is best characterised as a controversy. We will call them "socio-technical controversies"[38], as we will assume that the social and the technical are interwoven. Controversies are generated by technical as well as social uncertainties. Drawing a distinct line between these two aspects *a priori*

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[35] Based on Gilbert C., " La fin des risques ? ", *Quaderni*, vol. 48, automne 2002, p.118.

[36] Parts 1 to 3 are mainly based on : Callon M, Lascoumes P., Barthe Y., " Agir dans un monde incertain : essai sur la démocratie technique ", Seuil, Paris, 2001,

[37] One should note that a state of total ignorance would prevent any discussion and action since by definition we would not know that we do not know.

[38] To simplify, we will often use in the text the term " controversy " instead of "socio-technical controversy".

would be arbitrary, since this frontier is partly what is at stake in a controversy. We will therefore consider controversies as something flexible, the technical becoming social depending on the path of the controversy.

Socio-technical controversies have a dynamics of their own. Their path evolves in time and space and is, by definition, unpredictable, since it depends on the original degree of scientific uncertainty, and on the extent to which it is reduced in the process. By pushing towards the investigation of the unknown and by putting together different explanations of the phenomenon, controversies may help exploring the states of the world that are desirable in the future. Their main function is therefore to organise this investigation by generating information and confrontations of the diverse points of views. Which social groups are going to join the controversy? Which alliances are they going to make? Which technological options are going to be kept or, on the contrary, rejected by the research undertaken? Which new tracks of research are going to be explored? Here are some of the questions that are permanently formulated and re-formulated in the course of a controversy.

These dynamics can result in, either a reduction of uncertainties (from suspicions to presumptions and eventually proofs) or, conversely, in their increase. Besides, its engine lies in the dialectic between the technical and scientific research, on the one side, and the social reconfiguration, on the other side. Indeed, scientific investigations lead to the identification of new hypotheses on the causal relations, which allow the mobilisation of new social actors. At their turn, these new actors can propose new questions of research. This gives rise to a constant interaction between the social and the technical.

We will therefore assume that, in a context of scientific uncertainty, controversies can be simultaneously a learning as well as an exploring process. It has been observed by scholars that "hybrid forums" were one of the ways to achieve this double function of learning and exploration[39]. Here is a definition of this concept:

- "**Hybrid forums**" are public spaces ("agora") which are elaborated by the actors involved in a controversy to test organisational forms and procedures aimed at facilitating the collaborations between experts and lay people as well as at making visible and audible emerging groups that have no official spokespersons.
- "**Hybrid**" refers to the heterogeneous nature of the groups involved in this debate as well as their spokespersons, but also to the diversity of the issues debated (ethics, economics, physiology, atomic physics, electromagnetism, among others).

[39] This concept is developed in details by Callon M, Lascoumes P., Barthe Y., *op. cit,* , chapters 1 and 5.

- "**Forum**" refers to the open space where groups of people can mobilise themselves to debate technical and scientific choices that engage the collective.

Some of the main procedures that can take place to help framing controversies are listed here[40]. It is obvious that the capacity of such procedures to achieve their aim depends largely on the extent to which their results are finally integrated in the decision-making process:

**Focus groups**: they are structured but flexible group discussions exploring a specific set of issues of research interest. They normally bring together 3 to 12 individuals with a moderator who encourages interaction between the participants, promotes deeper exploration of questions and issues raised, and ensures that the discussion remains focused on the topic of interest. Originally developed predominantly for market research studies to record public responses to specific policies or consumer products, the method has increasingly been developed and promoted for social science research.

**Consensus conferences**: they are enquiries involving 10-16 citizens who are charged with meeting an expert panel and thereby carrying out an assessment of a socially controversial topic. Originally developed in Denmark, experiences of consensus conferences have also been made elsewhere (Norway, England, Holland, France, Canada, Australia, Switzerland) under other denominations: "citizen conferences" in France and "publiforums" in Switzerland for example.

**Publiforums:** In that case, about thirty volunteers - men and women, both young and old, of various professions and who come from all parts of the country - form a citizen panel. This panel of "laypersons" takes an in-depth look at a particular area of technology, for example genetic technology in nutrition. During two preparatory weekends, the panel members get to know each other. They are provided with information material by the organisers and decide on which questions they want answering by the experts. On the basis of a list of specialists who are willing to place themselves at the panel's disposal, the panel chooses around 20 experts who have to answer these questions. The actual Publiforum usually lasts four days. During the first two days, specialists and panel members meet to discuss the questions posed. These hearings are open to all interested people. After the discussions with the experts, the citizen panel leaves to make its decisions: on the basis of the information and answers received, it draws up a report, which is then presented to the general public on the fourth day. This report represents the citizen panel's view on the problem area addressed and makes recommendations for action for decision-makers in politics, science, business and administration[41].

[40] Taken from " Citizen Foresight : a Tool to Enhance Democratic Policy-Making. 1 : the Future of Food & Agriculture ", University of East London and the Genetics Forum, January 1999. And Marris C., Wynne B., Simmons P., Weldon S., *op. cit.* , p. 20.

[41] Definition taken on the Swiss Technology Assessment website at :

http://www.ta-swiss.ch/www-remain/projects_archive/publiforum/publiforum_e.htm

**Citizens' juries**: The Citizens' juries and the closely associated method known as Planning Cells were both developed during the early 1980ies in the US and Germany respectively. The process has similarities to the consensus conferences described above but with five key differences. Juries are selected at completely random, usually from the electoral register. Jurors are paid to attend the hearings. Information that is provided to jurors must come from several points of view, usually via witnesses. Witnesses are chosen by agreement of representatives from all stakeholders or by the jurors themselves. Though desirable, no consensus is required. Minority views are also normally recorded. The size of juries has normally been 12 (though sometimes up to 24) in the US and 25 in Germany.

## 4.3. SOCIO-TECHNICAL CONTROVERSIES AS AN EXPLORING MODE

Socio-technical controversies are a way to explore the "overflowings" generated by the development of science and technology, be they social or technical. These overflowings consist in the unknown effects generated by new technologies. They reveal unexpected issues to both the public and the experts and generate controversies. We will argue that the study of controversies may be useful, since it helps making a triple inventory:

1. They help identifying **concerned groups**. Groups may be concerned in two ways: because overflowings threaten their existence and identity, or because they voluntarily engage themselves in scientific and technical matters.
2. Controversies help identifying the **links between the issues** posed by the overflowings as well as the links with other issues. In other words, they make easier the realisation of an inventory of the diverse stakes of the issue.
3. They favour the **identification of the solutions** to these overflowings. In addition to the experts, these solutions can be formulated by the concerned groups themselves.

An example of these three modes of exploration is the controversy over GMOs in Europe:

- Consumers groups, environmental non governmental organisations (NGOs), farmers' unions and agrochemical companies emerged as concerned groups because their identity was threatened in different ways. The first ones argued for example that this technology was likely to expose consumers' health (e.g. allergies). NGOs argued that GMOs were generating risks for the environment. As for farmers, most of them feared financial losses in case consumers would not buy GM food. And agrochemical companies were concerned because they had to recoup the investments made in the research and development of this technology.
- Links between GMOs and other issues such as the patenting of living organisms or the socio-economic conditions of small farmers in developing countries were made by NGOs and farmers' unions, among others.
- And eventually solutions were formulated by some of the concerned groups. Consumers groups proposed the labelling of GM food, while environmental NGOs and some farmers proposed the development of organic farming. Another example is the attempt to develop a more "socially robust" transgenic vine by the French "Institut National de

Recherche Agronomique (INRA)". In order to achieve this goal, wine growers, ordinary citizens, biologists and sociologists have worked together to define the condition for a better integration of such a GMO in the sometimes contradictory objectives of the stakeholders[42].

## 4.4. SOCIO-TECHNICAL CONTROVERSIES AS A LEARNING PROCESS

In addition to their function of exploration, socio-technical controversies favour a double learning process that allows the overcoming of the double delegation of power, i.e. from lay people to experts and from citizen to their representatives[43].

The **first** learning process addresses the division between lay and experts in the production of knowledge. It assumes that experts do not have a monopoly in this field. When controversies take place in hybrid forums, experts have the opportunity to learn from lay people, who have a specific knowledge, that are a capacity of diagnosis, a capacity to interpret the facts and to propose solutions. Lay people are able to produce knowledge by performing "research in the wild" by opposition to confined research, i.e. research performed in laboratories. If this kind of research relies on universal and standardised methods, research in the wild relies on local knowledge and experience. Rather than being opposed, these two modalities of research can collaborate more or less intensely, depending on the field involved.

Four fields of collaboration can be identified[44]:

1. **The formulation of problems**, to what the sociology of translation calls the problematization phase. For instance, in the late 1960s, muscular dystrophies (MDs) were diseases about which little was known and for which there was no care and no cure. Clinicians and researchers were disinterested in them; strictly speaking MDs were outside their field of vision. The only knowledge, at first private and virtually secret, was that elaborated and accumulated by the patients and their families. By grouping together, patients were to share their knowledge and engage in a process of collective production, what is called the primitive accumulation of knowledge.

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[42] More information on this project can be found at the following site : http://www.inra.fr/Internet/Directions/SED/science-gouvernance/ITA-Vignes/

[43] These two learning processes are described in details by Callon M, Lascoumes P., Barthe Y., *op. cit,* , chapters 3 and 4.

[44] Callon M., " Researchers on the wild and the rise of technical democracy ", paper presented at the *Knowledge in Plural Context* Summer school, Science, Technology and Society Studies in Switzerland, Lausanne, September 2001.

2. **The direct and active intervention of concerned groups in the choice and monitoring of research subjects and thrusts**, and in the actual organisation of the research collective and the different sub-communities comprising it. A recent example of this collaboration is the participation of people infected by HIV/AIDS to the designing of the protocols used in clinical trials to test new anti-retroviral drugs. By progressively acquiring knowledge on their disease, some of the patients have become credible interlocutors of the scientific community.
3. Researchers in the wild and confined researchers can collaborate in **the transposition of results obtained in the laboratory**. Brian Wynne has showed this in his research on sheep farmers faced with the Tchernobyl cloud in the region of Cumbria in England[45]. In the aftermath of Tchernobyl, authorities in England decided to temporarily suspend the commercialisation of sheep for safety reasons. Their predictions were based on geological knowledge elaborated according to laboratories standards on the basis of observations collected from soils coming from another region of England. Thus, their composition (alkaline) was different than the composition of the soils in Cumbria. Experts had to revise the duration of the interdiction, from three weeks to several weeks, since it became quickly evident that the contamination of the ground was not decreasing. This example shows that laboratory knowledge is not transposable to real conditions without adjustments. In this perspective, the sheep farmers' knowledge of local conditions (i.e. the composition of the soil) would have been necessary to make better predictions.
4. Research in the wild is of particularly great interest for confined research in the **identification of dangers**. It can indeed function as an alert system covering a much larger territory than the laboratories or the classical expertise. In this case, researchers in the wild can be considered as sensors of dangers.[46]

We have seen that lay people and experts' knowledge can mutually enrich each others. This does not mean, of course, that lay knowledge should not be subject to the same intensity of critical scrutiny as specialist expertise.

The **second** learning process questions the second delegation of power, i.e. the delegation of power from the citizens to their ordinary representatives (i.e. politicians). It concerns the perception that actors have from each others, and should favour a better mutual understanding of the actors involved in controversies.

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[45] Wynne B., " May the sheep safely graze ? A reflexive view of the expert-lay knowledge divide ", in S. Lash, B. Szerszynski and B. Wynne, *Risk, Environment and Modernity. Towards a New Ecology*, London, Sage, 1996.

[46] Callon M., Communication at the meeting " Science, expertise et société ", Institut national de recherche et de sécurité, 19 novembre 2002.

Socio-technical controversies can be seen as a way to enrich representative democracy, especially when they take place in participative procedures such as hybrid forums. They may indeed become "laboratories" where new procedures, which put into question the classical division between the citizens and their representatives, are spontaneously designed and tested. Hybrid forums aim at making the debate on the composition of the collective world more open by giving to concerned groups – which have been until then ignored or excluded - the right to express themselves. They are spaces where procedures are tested, which should contribute to integrate uncertainty in the debate over the composition of the collective (i.e. the entities that have to be taken into consideration when one tries to determine the general will). This debate is indeed considered as an uncertain process, since its results are not known in advance. Indeed, with the help of controversies, new concerned groups emerge whose identities are progressively defined. In this process, they have to choose delegates or representatives, which they can withdraw at any time. Fearing to be withdrawn, these representatives may better take into account the views and opinions of the group. And it is more likely that they address the issues that concern the group and that they defend its interests in a better way than in the classical system of representative democracy. In this case, representatives are indeed elected, which gives them the mandate to speak in the name of their representatives for the duration of their mandate, with the risk that they end up defending their interests rather than those of their citizens. Hybrid forums help therefore preventing the predominance of a system in which politicians' interest – their re-election – tends to prevail over the citizens' interests. Through hybrid forums, representatives may be closer from the people they represent. And this may indirectly generate the progressive erosion of the opposition between supporters of the general interest and those of selfish interests.

Besides, to achieve their goals the procedures elaborated in hybrid forums should favour three processes:

- The constitution of the identity of emerging groups.
- The capacity of each of these emerging groups to recognise the existence of other emerging groups, and to take their existence into account in their own action.
- The will and possibility to negotiate in common the composition of the collective world.

These three processes should ideally result in the possibility, on every side, to re-define the identities, opening the way for new alliances and compromises that would have been impossible without the existence of the controversy.

# V. CONCLUSIONS

It is worth recalling synthetically the main points that have been addressed throughout our analysis:

- Industrial societies have produced new risks such as major technological risks, food and sanitary risks, environmental risks. These risks have an endogenous character, either because the functioning of modern societies (institutional or economical logics) amplifies them, or because they are directly the result of technological development (e.g. biotechnology).
- A schematic distinction has been made between two categories of risks, "known risks" on the one hand and "hypothetical risks" on the other, to which should correspond two different public policies, prevention and precaution. *Known risks* are risks whose relation between a cause and an effect is established, while *hypothetical risks* are risks whose probability as well as relation between a cause and an effect are not established.
- Nevertheless, reality offers generally a subtle and complex mix of clues, signs, information, correlation and partial proofs that cannot easily be fitted into the somehow artificial distinction between known risks and hypothetical risks, and consequently between prevention and precaution.
- The classical risk management model is composed of two stages, risk assessment and management. They are performed separately by experts and decision-makers. Experts are not as neutral as some might think but are oriented by society. They are indeed actors who are mandated by others, most of the time politicians, to provide basis for setting values, threshold levels and acceptable risk levels.
- The classical risk management model is confronted to another limit: it is not working when applied to some of the new risks as defined before. Important scientific and socio-economic uncertainties remain indeed in their assessment. Therefore, new procedures are needed that should help going beyond the double delegation on which the classical model of risk management is based: the delegation from lay people to experts in the risk assessment, and the delegation from citizens to their representatives in the risk management.
- The "overflowings" generated by the spread of these new risks give rise to controversies which have a crucial role to play. It has been observed that they can be simultaneously an exploring as well as a learning process.
- In this perspective, hybrid forums are "agora", which are more or less spontaneously elaborated by the actors involved in a controversy to test new organisational forms and procedures. These procedures should aim at facilitating the collaborations between experts and lay people in the production of knowledge (so as to overcome the delegation of power

from lay people to experts). But also at making visible and audible emerging groups that have no official spokespersons (so as to overcome the delegation of power from citizens to their representatives).

- To conclude, we have assumed that new ways of managing risks were needed to address the emergence of the new risks and their uncertainties (scientific but also economical, social and political). Having shown that the traditional risk management was inadequate for these risks does not mean, however, that it is not working for technologies generating known risks. On the contrary, the two approaches could co-exist, at the condition, however, that the traditional risk management be reformed in a way that allows the taking into account of its limits, i.e. its narrow conception of expertise.

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