



Presidenza del Consiglio dei Ministri
NATIONAL BIOETHICS COMMITTEE

**THE PRECAUTIONARY PRINCIPLE: BIOETHICAL,
PHILOSOPHICAL, LEGAL ASPECTS**

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Premise

In the last few decades, as is known, several episodes have given rise to deep concern for the protection of the environment and the human habitat, human safety and health. They are, to name just some examples, major ecological disasters (the sinking of the tanker Amoco Cadiz, Prestige), the release in the environment of chemical or toxic products (Bophal 194, Seveso 1976, Mexico 1988), the leakage of radioactive material (Three Mile Island, Chernobyl), the explosion of industrial plants (Toulouse, 2001), the alterations in the food chain, also due to accidents (according to the imaginative language of the “media”: mad cow), etc.

This led to:

- 1) the growing focus of public opinion on the potential implications (also long-term) of the current model of technological and industrial development;
- 2) a climate of progressive mistrust towards public control mechanisms
- 3) the need for governments to identify new principles (also with regards to procedures) able to facilitate, on the one hand, the assessment and containment of the risks and, on the other, their management not only for the purpose of their social acceptability, but also to enable truly sustainable development.

It must be clarified that the severity of the episodes mentioned above, some of which reoccurring with a different intensity over the years, has sometimes caused emergencies and catastrophic events, but at other times only emerged long after the manifestation of the risk linked to the event in question, giving rise to “delayed” health or ecological consequences, the causal connection of which has been ascertained.

And it is significant to highlight that the current epidemiological research increasingly emphasises the fact that even contained levels of risk, and agents globally defined as toxic, can operate with an effect of so-called accumulation, both combining simultaneously with other risk factors (also of a genetic type), or at work for a very long time, so that they cause, even after a long time from exposition, manifestations of pathologies in humans, that is, harmful effects and damage to the environment.

It emerges in this way a different dimension of risk, more subtle and not only qualitative T (“toxic”), but also quantitative, which reaffirms the fundamental need to precede industrial development with a more articulated phase of research, in which, as demonstrated by experience, it is easier to achieve the margins of safety necessary to verify the initial scientific hypothesis.

These pressures produced two types of consequences: on the one hand, the citizens’ demand to be informed in advance and participate in decisions that affect both technical-scientific development and industrial growth. Attention must also be given to the public opinion’s preoccupation about the possibility of leakage of toxic or radioactive products from the appropriate facilities (cf. the recent case of Scansano Ionico), on the other hand, governments’ greater awareness to take into account behaviours and decisions aimed to prevention, where possible, or to the “new” precautionary principle, if there are significant margins of uncertainty about the relationship between the risks and harmful consequences of certain activities (or procedures or products) for humans and the environment. Thus, in addition to approaches inspired by the so-called zero-tolerance, it has been established the need to carry out a more careful

evaluation of the proportion between risks and benefits, capable of guiding the technological-scientific development, which is still necessary for mankind's material and social progress, according to a principle of mediation between the different needs and attitudes of science, industry and civil society.

From a bioethical point of view, the above considerations call into question not only and obviously the general principle of responsibility, but also and especially the need to combine this principle, usually attributed to governmental bodies, with a shared common sense, in order to identify a new "governance" of civil societies aimed at supporting preventive rather than reactive actions.

To contribute to the surfacing of a more mature sense of responsibility in public opinion, the NBC has seen fit to investigate – in this document – some ethico-legal aspects affecting the so-called "post-industrial society", which is developing a new awareness of risk and of the control of some of its expressions through the "precautionary principle".

The NBC, which has already in the past dedicated its attention not only to the issue of safety in biotechnologies, with special regard to the release of genetically modified organisms in the environment (which at the moment of expressing an "opinion" was debated and of current actuality, 1991)¹, but it also dealt with the properly medical "risk" inherent to the clinical activity of a single individual (see the document "Aims, Risks and Limits of Medicine, published on the 14th of December 2001)², now intends to examine the general issue controlling the application of the "precautionary principle" from a dual point of view: environmental safety; collective health protection (public healthcare), namely, environmental health. This investigation will be conducted with specific reference to the international and European Community context, more sensitive to the solicitations underlying the application of the precautionary principle than the Italian context so far, which however recently saw the adoption of legislative measures inspired to the principle under examination. Amongst these measures, which may be examined in a future document by the NBC, it is possible to recall for example law n. 36 of the 22nd of February 2001, on the protection from exposure to electric, magnetic and electromagnetic fields, which contains, in art. 1, an explicit reference to the "precautionary principle", or the Decree of the Ministry of Health of the 22nd of November 2000, which declares ineligible to donate blood all individuals who stayed in the United Kingdom for a few months between 1980 and 1996, also based on the precautionary principle.

From this perspective, the first part of this document will outline in broad terms the "scenario" of the "precautionary principle". After recalling the factors that contributed to the notion of "risk society", established in the current use regardless of its doctrinal elaboration³, we will try and highlight the ways in which modern technical-scientific research perceives the risk within the applications of human activities and how it deals with it when it is unable to quantify it with sufficient probability.

Therefore, we will examine criteria of risk identification and assessment, with the objective of protecting the collective safety-health, taking into account the criteria adopted by "experts", as well as, in other ways and giving them the right importance, the views widespread in public opinion and amongst the

¹ National Bioethics Committee, *Safety of Biotechnologies*, Presidency of the Council Ed., Rome, 1991.

² National Bioethics Committee, *Aims, Risks and Limits of Medicine*, Presidency of the Council Ed., Rome, 2001.

³ Cf. U. BECK, *Risikogesellschaft*, 19XX.

citizens-users. In the second part, we will instead examine the social tools (philosophical, legal and organisational) through which contemporary society reacts when faced with risks in the vast field of the human activities considered. This analysis will be conducted, in particular, in light of the criteria developed by the law in order to illustrate the action tools provided to policymakers. To this end, a further warning seems appropriate: the investigation by the NBC is as far as possible limited only to the illustration of the “precautionary principle”.

Moreover, in the document, you will encounter extremely important concepts, which it is not possible to linger on in this document: we cite for example the issue of “sustainable development” or that of the organization of legislative powers on the environment, which in the new version of art. 117 of the Constitution are vested in the State with the formulae “protection of the environment, ecosystem and cultural heritage”.

This warning – in any case – interests the discussion of the “precautionary principle” in so far as – as the strategy of primary protection of the environment is entrusted to the State due to a European Community regulation – also the concrete application of the precautionary principle on issues that are environmental in the widest sense, is due to the State. The fact remains that a cautious approach should guide every individual to consider the effects of his/her actions towards the environment!

The NBC investigation, the results of which are aimed primarily at a public opinion now made more aware and mature by the events mentioned, intends to state that the current technological society should increasingly equip itself to assess and prevent the risks accompanying its development and that, if a true prevention is not possible, should adopt, in view of a rational allocation of resources, at least more suitable measures from a precautionary perspective, to immediately ascertain not only the occurrence of phenomena producing adverse effects – the causes of which must obviously be removed – but most of all to monitor those activities that could, in the absence of conclusive scientific evaluations, prove to be feasible only with great caution and only if they anticipate limited risks, waiting for solid scientific evidence.

The precautionary principle attracted a lot of criticism and raised contrasting opinions⁴. Amongst the concerns expressed, there is in particular a “political inference in the open and free discussion of not yet well defined scientific arguments; but in effect it is the precautionary principle that will hold back economic development, in particular in developing countries, and that could lead to an imbalanced if not distorted discussion on environmental risks” (With an overestimation of the chemical or nuclear risks in comparison to the more common and therefore more accepted ones as road accidents). In response to these criticisms, other authors argue that the precautionary principle, and in general a policy of regulation, contributed both to the development of new technologies and cost reductions.

In conclusion, in line with the development of a culture of collaboration, it is necessary to identify the convergence of will and action in some key parts of society: decision makers, scientific experts, “informed” public opinion, financial operators.

It must be stressed from the outset that the application of the precautionary method intends to produce not an interruption, but rather an

⁴ Cf., for example, the recent controversy in *Nature* magazine (425: 663-4, 2003; and 426: 227, 2003).

increase in scientific research activities, by overcoming critical issues and removing the uncertainties that currently make it difficult to reach the level of clarity necessary to allow or apply a policy of prevention (which would even lead to prohibit certain activities when the gravity of the risk cannot be improved) or the development of systems that, as far as possible, can minimise the situation of risk, making it compatible with economic (sustainable) development.

CHAPTER I

The social outlook

1. The “risk society”: brief outline of the widespread feeling of risk

In recent decades, the theory of the “risk society”, which would characterise the era in which we live, is strongly taking hold.

We cannot deny that, even in the past, it affected the often un-measurable relationship between the advantages of bold individual action and the risk of damage and loss deriving from it, but it is undeniable that the evidence with which this dilemma is introduced in a more enveloping and social dimension, leads to consider it a recent dilemma.

Theorisations on the relationship daring/risk can be found – for example – in Condorcet⁵ in the essay on the progress of the human mind; in Kant⁶ in “Idea for a universal history from a cosmopolitan point of view. Gleanings of political philosophy” and more recently in Emile De Girarden⁷ in “Politique universelle” and finally in Luhmann⁸ and other authors.

This evolution seems to have several components that can be briefly summarised as follows:

1) – First of all a moral philosophical interpretation of the notion of risk has been refined but also generalised – breaking away from and expanding the notion of “danger”: existing is already a risk; choosing the values to live by is a risk; transforming man in a “human act” is a risk (Ewald and Kessler, 2000)⁹; any vital – and unavoidable - involvement of the individual is essentially a risk. Already Blaise Pascal¹⁰, linking in a metaphor the notions of betting and risk, wrote: “You must wager. It is not optional. You are embarked”.

2) A considerable contribution to the understanding of the phenomenon of accepting risk as an ordinary condition “searched for” by mankind has been given by anthropological reflection. An authoritative trend recognized human reactions when faced with the uncertainty of the future (which has always existed) “from practicing divination which, although it could not guarantee reliable certainty, could in any case guarantee that our decision did not anger the gods or other divine powers and was instead protected by the contact with the mysterious forces of destiny” (Luhmann, 1996)¹¹, as a model of the game that would always rule the real world (Huizinga, 1967)¹², just as it rules dice combinations (“chance”, in fact).

Starting with this interpretation, R. Caillois, 1981¹³, stated that the pair “agon” (competition)-alea (chance) structured all western civilisation: “western man, putting risk at the centre of his actions, produced a process of civilisation

⁵ CONDORCET- quoted by F. EWALD e D. KESSLER, *The typology and policy of risk* , in “Risk” Key words, 2000.

⁶ KANT I., *Idea for a universal history from a cosmopolitan point of view, Gleanings of political philosophy*, La Nerva, 1973, Firenze, Italia.

⁷ DE GIRARDEN E., *La politique universelle*, Brussels, 1982, pp.16-17.

⁸ LUHMANN N., *The notion of risk* , in “Risk”, n. 22/23/24, Key words, 2000.

⁹ EWALD F., D. KESSLER, *The typology and policy of riskin* “Risk”, Key words:,n. 22-24, 2000.

¹⁰ PASCAL, *Oevres completes*, Gallinard, Paris, 1936, p.1213.

¹¹ LUHMANN N., *The notion of risk*, in “Risk”, Key Words, n. 22/23/24 December 2000.

¹² HUIZINGA J., *Homo ludens*, Il Saggiatore, Milan ,1967, p.14.

¹³ CALLOIS R., *Games and Man. The mask and the vertigo*, Bompiani Ed., Milan 1981.

in which the model of the game is at the root of the law, both in the definition of fair rule (justice) and in how we play (the process)". (Ewald and Kessler, 2000).

3) – An important innovative contribution consists in the use of the notion of "objective measure" of the risk, linked to the advent of probability calculations (P. Bernstein).

It has been rightly said that this form of mathematical rationality participates to the genesis of the modern notion of risk: "There is no risk without a certain form of calculation, analysis, expertise: it is a form of knowledge" (Ewald and Kessler). The development of the objective measure has emphasised the need to compare the risks, and it has consequently highlighted the inexistence for "zero risk". Acting is a risk, but also not acting – in certain conditions – is not avoiding risk, but introducing one that can also be quantifiable.

4) – The risk, born from the game theory and objectified by the calculation of probability, has become sociologically a theory of modernity, a theory capable of assessing the value of acting using the ethics of responsibility, which requires each of us to make judgements on the morality of our choices towards others.

It has been acutely observed that in this dynamic, the economy has derived all the benefits: this discipline has "the ambition to give, within the universe of risk, a general theory of its value and this starting with a decision theory.

The hypothesis made requires that, if the value is expressed through the choices of the acting individuals, they are dominated by the relationship they have with risk, by their more or less strong aversion towards it. When there is uncertainty, the value of values depends on risk". (Ewald and Kessler, 2000)¹⁴.

5) – On this broad basis, an explicit "sociology of risk" was created, and a deriving "theory of reflexive modernization", which has enjoyed a growing interest, although maintaining various ambiguous characteristics.

In extreme simplification, the theory predicts a reversal of trend with regards to the binomial "production of wealth" – "production of risk" in the sense that: "While in classical industrial society the logic of wealth production dominates the logic of risk production, in the risk society this relationship is reversed". (Beck, 2000)¹⁵.

This author continues: "The growth of the power of techno-economic progress is increasingly overshadowed by the production of risks. In a first stage they can be legitimised as latent collateral effects. But with their universalization, with the criticism by public opinion and (anti)scientific analysis, the risks emerge once and for all from their latency and acquire a new and central significance for social and political conflicts".

In conclusion, as it was already highlighted in the 80s by Niklas Luhmann, our society, because of its progressive differentiation, tends to take shape at every level as a risk society, which is more and more difficult to find unambiguous ethical or cognitive criteria to assess. Risk is something we cannot escape in any way, because it represents the essential feature of a complex society. And "complexity means a need to select, a need to select means contingency, contingency means risk" (Niklas Luhmann, *Social Systems*, Stanford, California, 1995). We can choose, in other words, if we run

¹⁴ EDWALD F., KESSLER D., 2000, l.cit.

¹⁵ BECK U., *Risk society. Towards a second modernity*, 1992.

this or that risk or even the risk not to choose, but we cannot avoid risk as such. To use a nice image by Niklas Luhmann, the first original sin condemned man to temporality, sweat and dangers of various nature, the second original sin, the “technological” one, condemned man to live at risk. Better therefore that we are equipped to live with the uncertainty of the unavoidable, even if “controllable”, rather than chase after a safety that is now impossible.

It is outside the scope of this analysis to assess every aspect of these reflections developed, as well as by Luhmann, especially by Beck (2000)¹⁶, Giddens (1990)¹⁷, Lash S. et al. (1996)¹⁸, Lupton D. (2003)¹⁹ and by other authors; but the NBC was interested, here, to draw attention to this attempt at sociological analysis as a sign of a desire to look in more depth at the relationship between the various “actors” of the social definition of risk: scientists (researchers, technicians, experts), jurists (relationship between law and science); philosophers (bioethics); politicians (mediators of sustainable development); citizens (public opinion).

2. Science between risks and uncertainty

Potential sources of risk associated to human action or inaction are inherent to any type of intervention and transformation wrought in the physical environment and on living organisms. It is therefore essential to arrive at a classification of the risks that exist, or are produced, by human actions that are the object of this review by the NBC.

Science has tackled this issue, which presents various aspects:

- How to classify the risks;
- Which tools the researcher has to identify and quantify the risks.

- Classification

According to a classification initially applied to the case of environmental risks, intended in the wider sense (collective safety, health, etc.), we can distinguish the risks that are certain, and can therefore be considered unacceptable from the point of view of caution and prevention, which express the link of causality between the event and the scientifically proven damage resulting from it; residual or concurrent risks, those relating to carrying out normal and daily activities, towards which we can only have tolerance; uncertain or supposed risks, which are however unproven scientifically, towards which it is not meaningless to suppose that they exist and that –therefore – only a precautionary attitude can ward them off (De Sadeleer, 1999)²⁰.

Modern reflection, obviously, focuses on this category, which – in the end – denotes the current lack of scientific certainty about certain issues that are being tackled.

¹⁶ BECK U., l. cit

¹⁷ GIDDENS A., *The consequences of modernity. Faith and Risk, safety and danger*, Polity Press Ed, Cambridge, 1991.

¹⁸ LASH S., SZERSZYNSKY B., WYNNE B. (Ed.), *Risk, Environment and Modernity*, London, 1996.

¹⁹ LUPTON D., *Risk: Perception, Symbols, Culture*, Routledge, New York, NY, 1999.

²⁰ N. DE SADELER, *Les principes du polluer-payer, de prévention et de précaution*, BRUYLANT/PUF, 1999.

The status of ignorance, like the absence of knowledge, was traditionally configured like a simple negative data, not better defined. But the need to predict the impact of new and potentially dangerous technologies prompted the search for a more detailed epistemological classification for the unknown. According to the recent report by the European Environmental Agency²¹ - which incorporates the distinctions already introduced by Brian Wynne²² - the lack of knowledge can have four different connotations: risk, uncertainty, ignorance, indeterminacy.

In the case of a decision under risk conditions, the variable characterising a problem is known and the respective probability of different outcomes, positive or negative, is qualified (known impacts, known probabilities).

In the hypothesis of a decision in uncertain conditions, instead, although the possible damage is known, the probability of occurrence is unknown (known impacts, unknown probabilities). The lack of knowledge refers to situations in which not even the negative event is foreseeable, nor its relative probability (unknown impacts, unknown probabilities).

Indeterminacy, finally, is the concept summarising the generally open and conditional character of all knowledge, in particular its contextual value, its socio-cultural determinability. Funtowicz et al.²³ and Ravetz have coined the expression post-normal science to identify situations in which “typically, facts are uncertain, values in dispute, stakes high and decisions urgent”. Unlike the “incremental” model – the science that progressively unravels the knots of knowledge – the idea of post-normal science considers uncertainty as the element that is co-essential to the science destined to public choices, the operative context of which is always linked to uncertain facts, conflicts of values and interests. A timely decision can be, if necessary, unavoidable.

- The uncertainty of scientific knowledge

It can be useful to briefly dwell on the concept of the “uncertainty of scientific knowledge”, which is definitely called into question when we want to identify and quantify the risk inherent to some of the more innovative human activities.

We see, in fact, an area of uncertainty in the knowledge of life sciences, and in particular in the relationship environmental-biotechnological sciences, also due to the speed with which new technologies are applied, according to some because of the impetus of the economic forces regulating the development of the industrial process.

These attitudes have repercussions also on the so-called “social impact” of science on public opinion, which is profoundly ambivalent towards the science and the safety of applying new technologies and on the efficiency of the relative public controls. The phenomena of the development of technology and science are for many reasons linked and it is therefore important to spend a few words of further investigation. With the expression “the uncertainty of science” we allude to various forms of indeterminate knowledge in science: the complexity of the knowledge, the lack or inadequacy of data, the

²¹ EUROPEAN ENVIRONMENTAL AGENCY, *Late Lesson from Early Warnings: the Precautionary Principle* (1896-2000, 2001)

²² B.WYNNE, *Uncertainty and Environmental Learning: Reconceiving Science and Policy in the Preventative Paradigm*, in “Global Environmental Change”, 1992, June, pp. 77-85.

²³ S.O.FUNTOWICZ, *Post-Normal Science. Science and Governance under Conditions of Complexity*, 1993.

unpredictability of the outcomes and the stochastic character of the predictions in many sectors of naturalistic investigation.

This means that ever more often and in many areas of the scientific community, called to pass judgement in relation to an issue of applied science or technology that needs legislative regulation, is not able to express a certain and unambiguous point of view, at least when questioned.

The always open character of the scientific journey is without doubt its defining trait, but the complexity of some fields of research radicalised this character towards different forms of uncertainty (Talluccini, 1996)²⁴.

The difficulties encountered in the development of scientific knowledge in the environmental and food sectors have particularly contributed to reinforce in public opinion the aspects of complexity and uncertainty of knowledge, in the awareness, in any case, of the strong social impact linked to choice, especially with regards to environmental health and food products: GM food is a classic example of this situation, as it gives rise to widespread fears about the consequences on the nature of the environment and food.

3. Some preliminary remarks on the attitude of the law towards scientific-technological applications and the risk problem

The tumultuous evolution of industrial society first, of risk society after, have profoundly affected also the direction taken by the law (always entrusted with promoting the harmonious development of society, in the respect of human values and interests) when faced with serious disorders in the environment, the ecosystem, in human safety and health, etc., which we have recalled above.

It seems clear – in the last decades – a profound rethinking of the relationship between the law and science in the field under investigation.

The most traditional relationship between science and law has developed in the name of an apparent neutrality between the two types of knowledge. This involved, for the law, the mediation of the so-called “technical regulations”: regulations in which the law simply gave legal effect to the contents (mainly technical and scientific) foreign to its competences (Giannini, 1973)²⁵.

Some phenomena are at the basis of a different awareness and a strong change in perspective, which is emerging in recent decades.

This regards first of all the effects created by the epistemologically recognised growing uncertainty of scientific “truth”; by the awareness gained by jurists of the specificity that characterises the regulation of environmental issues in a pluralistic society and finally also by the realisation – on the occasion of some environmental disasters – of the insufficient provision for the risks that applied science – entrusted to technocrats – should have taken into consideration before acting. The law, then, becomes the interpreter of people’s uneasiness for the uncertainty of life, the environment, health and the climate of suspicion that the increasingly aggressive character of research, with the manipulations of living matter, causes towards science “tout court”. In this way,

²⁴ TALLACCHINI MC, *Diritto per la natura. Ecologia e filosofia del diritto*, Giappichelli Ed. Torino, 1996.

²⁵ Giannini (Riv.Dir.penale, 1973, p. 44 quoted in Spantigati F., *La gestione della strategia ambientale*, Riv. Giur. Ambiente XVII, 245-257, 2002).

a radical subversion of the conditions that made possible the respectful, distant relationship between science and law has occurred.

Where areas in which technology – assimilated tout court to science – created relevant risks and has shown itself to be incapable of controlling them with the desired certainty, as scientific data are uncertain, insufficient, or susceptible to extremely different interpretations, the situations in which the law has to “integrate” science in its social function have increased.

In fact, more and more public opinion has felt it necessary for the law to intervene with protective measures for the citizens, when the possible verification of a damage has not been confirmed by science in its factual improbability.

All this constitutes the symptom of an important change in the epistemology of the legal regulation of the technology applied at the level of industrial realisations.

It is the passage from an acritical view of scientific knowledge, taken as objective and devoid of uncertainties, to a position of awareness of the non-neutrality of technological solutions, when they are in contact with production activities, which can affect safety, the protection of the environment, living creatures, man.

In any case, the law in its jurisprudential expression traditionally based on a view of “certain science”, deterministic in its causes and consequentialist in the effects – tends today in the environmental field to adopt the encoding of methods defined by some as “good science”, as they are not only validated with technical procedures, but characterised also by a democratic participation to decisions, realising – in essence – a relationship of co-production due to the cross between knowledge that occurs in the confusion of the boundaries between various systems (Jasanoff, 1990²⁶, Tallacchini, 2002)²⁷.

This attitude outlines an approach to the management of science as answer to the crisis of confidence by citizens, aware of the errors made in the field of health and safety committed by the government. The repetition of events, in which the collaboration between these scientific experts (or scientists) and policy-makers appeared inadequate to manage situations of uncertainty also in Europe, has made the problem of trust of the civil society in science a crucial one. The idea of “science destined to public purposes” is in this way assuming precise theoretical and operative outlines (policy-related science, De Marchi and Tallacchini)²⁸: a notion that, although recognising the privileged character of the language of science, it is aware of the political nature of social decisions about science. The science linked to, and implicated with, public choices reveals a peculiar methodological status, having to contribute to defining issues that, with regards to society, are connected to much broader evaluations, also where they receive a scientific-technical formulation.

This is a definite model of public, civic science, the legitimate management of which entails both an extension of scientific expertise and the citizens’ participation in decision-making processes.

²⁶ SHEILA JASANOFF, *The Fifth Branch. Science Adviser as Policymakers*, Harvard Univ. Press, Cambridge, Mass, 1990.

²⁷ TALLACCHINI MC, *Giudici, esperti, cittadini: scienza e diritto fra validità metodologica e credibilità civile*, Quaderni di Politeia, XIX/70, 2003, pp.83-94.

²⁸ DE MARCHI B., TALLACCHINI MC, 2002, l.cit.

During this evolution, which could begin – at least in Italy – with a reflection on the Seveso (1976) episode, the law has developed – in any case – procedural and substantive regulations that are increasingly analytic and “penetrating” for the protection of the environment and human health, fundamental “targets” of “public science”, the detailed analysis of which is beyond the scope of this document.

Italian policies have also – in these last decades – offered numerous contributions to:

- the classification of the provisions in relation to the production systems of environmental technical regulations;
- the identification of the issues, also constitutional, that the growing recourse to environmental technical regulations involves.

In turn, the Courts focused on environmental technical regulations in two situations, different from each other:

- when damage has already occurred, and it is about establishing if there is a responsibility;
- when we want to prevent a certain activity, for fear that damage could occur: and therefore it is about establishing whether the fear is founded, or, more exactly, if what is known and certain about whether the fear is well-founded, justifies a prohibition.

Often, as we can easily imagine and is in part inevitable, the level of scientific investigation in these circumstances it is not entirely satisfactory.

But most of all in the European Community, we have made an effort to elaborate – in theory – the “principles” adequate to set up the action of the individual states and guide it towards reaching common levels of protection (see in attachment the definitions of the principles of user/payer; polluter/payer; prevention; mitigation; precautionary; sustainable development, etc.).

Let’s not forget that – in Europe – the protection of the environment finds its foundation in art. 174 (ex art. 130 R) of the Treaty establishing the European Community on the basis of which European Community environmental policies aim at a high level of protection, taking into account the diversity of the situations in the various regions of the European Community.

The protection is founded on the precautionary and preventive action principle, on the correction principle, first of all at the source of environmental damages, as well as on the principle that “those who pollute, pay” (Pozzo, 2000)²⁹.

The “cautionary criteria” resulting from ecological instances – also as an ethical need of hesitating towards non-repairable damages – resulted in any case in the necessary preventive evaluation of the risk, and of all the effects that human activity (assessment of the environmental impact, first of all) has on the environment (intended in the broadest sense).

As clearly say Vineis et al. (2002)³⁰:

“Mainly, we can take two attitudes faced with a choice regarding environmental risks when we don’t have reliable information. The Environmental Impact Assessment has a neutral attitude towards the risks and it includes the uncertainty of the calculable risk in terms of statistical probability

²⁹ Pozzo B. *Verso una responsabilità civile per danni all’ambiente in Europa: il nuovo libro bianco della Commissione della Europea*; Riv. Giuridica ambiente XV2000, pp. 623-665.

³⁰ VINEIS P., GHISLENI M., *Rischio, scienza, giustizia*, in Notizie di Politeia XIX, 2003, pp. 75-82.

(assuming that we can always reach an objective scientific opinion). Instead, the Precautionary Principle does not claim to be neutral faced with a chronic lack of information, but it rather expresses a clear bias in favour of a careful monitoring that can lead to times of inaction (that is, it recognises the epistemic importance of scientific ignorance and it accepts it as a data of knowledge amongst others)”.

We will develop the “rational” and the theme of this principle in more detail in chapter III of this document.

One last, brief note seems appropriate with regards to the role and characteristics of the “expert”, who – in this new structure of governance – has certainly not abandoned his/her role as scientific mediator of the policy-maker, even though it is at his/her level especially that the role has changed.

4. The policy-maker, the characteristic of the expert and expert advice

It seems appropriate, now, to briefly examine this relationship. We have already highlighted the fact that administrative-political decisions often have to be taken in a context characterised by significant risks and by scientific knowledge that seems particularly incomplete or uncertain in the cases studied.

Frequently the decision-maker finds it difficult to know (identify exactly) the facts or to interpret them, because, according to Barre³¹:

- lacks in knowledge (at least sufficient knowledge) of the biological, chemical, etc. processes susceptible of determining direct consequences of various nature;
- has problems in identifying indirect effects;
- has uncertainties about the applicability of the scale of the real world to laboratory experiences;
- has difficulties in identifying the groups of interest that could be mostly exposed to the consequences deriving from the abovementioned uncertainties.

Despite the reservations that recently have developed towards the experts, for the decision-maker, expert consultation is an irreplaceable practice. Adopting, for the sake of brevity (and because it has become part of the Italian linguistic habit) the expression “expertise”, we will recall that this is the production of a specific knowledge for action, designed in any case according to the ideal model of rational decision: it is a procedure destined to give elements of clarification to an authority that has the task of taking responsibilities and decisions.

The expert, in principle, is the one who has a particular knowledge recognised within a given profession and it is for this reason that he/she is called to offer the policy-maker his/her knowledge.

If the definitions are clear, the practice is sometimes less straightforward, in the “choice” of the expert (inside or outside the administration, etc.), in his/her real “competence” regarding the specific problem under consideration, in his/her complete “independence” from the political power, etc.

³¹ BARRE' R. *Expertise et avis scientifiques: les dangers des pseudo-sciences et des pseudo-politiques* – The IPTS Reports. Institut de prospectives technologique (IPTS) Commission Européenne N° 60, December 2001.

Therefore, a functional “characterisation” of the figure of the expert has gradually developed (eventually valid also for legal purposes when the expert is called by a judge), which in continental law responds to the following elements:

- independence from the decision-maker; recognised authority (in relation to his/her unquestionable specific and/or technical competence); neutrality from the emerging interests of the issue under consideration; personal integrity.

In Anglo-Saxon Law, the expert is rather a partial “advocate”, and the expertise is conducted in accordance with the adversarial principle, whilst requiring that the expert remains objective and loyal in the framework of his/her competences.

In any case, the expert must respect the deontological rules of his/her profession, correctly express not only personal opinions, but also those resulting from the experience of others (in literature); have the right to carry out his/her mission in freedom, without being eventually removed; being able to publish (make known) his/her opinions to the public.

It has now become common practice to nominate “expert committees” including different disciplines and with members inspired to different cultural trends, in order to overcome the various objections that the public opinion addresses to politicians-administrators.

More and more often, representatives of environmental associations are also invited and “FORUMS” are organised to collect opinions valid to contribute to the decision-making.

It must be emphasised that – in any case – the ultimate responsibility for the decisions belongs always to the administrators and the politicians, even though we should not minimise the responsibility of those who give the opinions that form the basis of the decision.

In conclusion, much has been discussed in recent years, about the “expertise” process, with regards to environmental risks, of the introduction of new industrial and food technologies (see for example the case of GMOs). Whilst some schools of thought strongly defend the “scientific” characteristics of the expertise, according to a rational method that is not influenced by socio-political opinions and believe that an eventual “reversal of proof” – where introduced by law – would prevent the possibility of establishing a difference between an hypothesis and a simple assumption, to destabilise the current technical-scientific culture and create a conceptual confusion that is regressive for society, other schools of thought argue the benefits of participating to the procedures of expertise of that “common knowledge”, which matures more than we realise in public opinion, and it allows the enhancement of communication, the clarification of uncertainties and suspicions towards a haughty and paternalistic science, the restoration of the lack of reliability. In this way, the policy-maker meets the demands of public opinion and – a fact that has been judged of no little interest – experiments new forms of governing and possible worlds.

The “philosophy” of this last approach is based – in any case – on the recognition that science, certainly, remains a relevant form of knowledge to resolve the risks of the practices and technologies that affect the community, but it is not the only one.

The citizen does not want to be excluded from the decisions that affect his/her “quality of life”. On the other hand, in countries with a high technological standard, there are amongst common people (as those who do not belong to

the decision-makers are often called) many people who are scientifically prepared and experts in various professional fields, able to speak on an equal footing with official “experts”.

Treating these people as ignorants is not only politically wrong, but ineffective and counterproductive because it wastes a potential which could, in the right proportions, be of considerable use in a democracy.

Finally, the way public opinion perceives risk is, in general, more extensive than that of the experts, and it covers hypothesis that sometimes are overlooked by the experts, but on which it wants answers. All this still moves in the realm of reason and it has nothing to do with “panic attacks”, or especially with motives (for example to ward off economic competition) that are passed off as “risks”.

The policy-maker has every interest in finding new forms of compatibility with widespread reasonable opinions (“governance”) (S. JASANOFF, 2003); LIBERATORE and FUNTOWICZ, 2003, etc.); on the other hand it cannot know whether, and in what time – science (research) will be able to resolve uncertainties, whilst it is urgent to give a precise guide to the questions asked (CHRISTOFOROU, 2003).

The “precautionary principle” operates in this context, and – in certain circumstances – it can represent that mediation that the policy requires to avoid dangerous fractures amongst the so-called decision-makers and those who are involved in other people’s decisions (DE MARCHI, 2003; CHRISTOFOROU, 2003; TICKNER and WRIGHT, 2003)³².

³² JASANOFF S.,(NO) *Accounting for expertise*,in “Science and public policy”, 30/3, pp.157-162, 2003; LIBERATORE A., FUNTOWICZ S., *Democratizing expertise, expertising democracy: what does this mean, and why bother?* in “Science and public policy” 30/3, pp.171-176, 2003; CHRISTOFOROU T., *The precautionary principle and democratizing expertise: a European legal perspective* in “Science and public policy” 30/3, pp. 205-211, 2003; TICKER J.; WRIGHT S., *The precautionary principle a democratizing expertise: a US perspective*, in “Science and public policy”, 30/3, pp. 213-218, 2003; SJOBERG L., *Factors in risk perception* in “Risk Analysis” 20, 1/6, 2000.

CHAPTER II

Ethico-philosophical evaluations of the “precautionary principle”

The “precautionary principle” comes from the request to “act with a precautionary approach” in order to protect the environment (Rio Conference, 1992: “United Nation Conference on Environment and Development”) and it invites to analyse the notion of precaution together with that of caution and responsibility.

In common language, there is a considerable “interchangeability” in the use of the expressions “caution” and “precaution”, which however are not equivalent in the history of thought.

In philosophy, the term “caution” indicates the ability for wise deliberation, and corresponds to the Greek *phronesis*, sometimes translated directly as “wisdom” (Piefer, 1999)³³.

The concept of “precaution” can be considered as the application, in certain circumstances, of the virtue of caution to concrete decisions, which require (after careful analysis) an attitude of care about the possible consequences both of the action, as well as inaction.

If the term “precaution” has rapidly disseminated in the legal and biolegal spheres (as well as in the media), the same has not happened in philosophy. Philosophers are reticent to use this expression: only recently a bioethical discussion is developing on this principle, or rather, on the precautionary approach to bioethical issues. The reticence can maybe be explained by the novelty of the language, not easily placed in traditional philosophical categories (like wisdom and caution). The problem is that if the traditional categories (although theorised in a different way by different thinkers) in some measure offer a contribution to the explanation of the meaning of precaution, they are not however enough to rigorously frame the principle, which has been specifically seen in the context of the recent issues emerging in bioethics and biolaw, with particular reference to human health and the protection of the environment.

If we start from the more general semantic value of the precautionary principle, that is, the exhortation to have a careful approach with regards to the speed and unpredictability of the development of technical-scientific progress when faced with the perception (even only intuitive) of the possible negative consequences and with the foreshadowing of possible future damage, we can say that this principle coincides with bioethics, born precisely from the ethical need to reflect on the legality or illegality of certain practices and interventions of manipulation of life in general against the naive permissiveness of technological science. In a sense, we could say that the precautionary principle, in its general validity, comes from the same context as bioethics, namely, within the reflection on the issue of man’s relationship with nature when faced with the onset of an increasingly close link between theoretical knowledge and practical applications. This reflection was prompted by the emergence of the awareness that the effects of certain manipulative interventions on life (human and non-human) can affect the most intimate composition of reality, causing an alteration of individual and specific human identity, as well as an irreversible modification of other animal and vegetal living species, with the eventuality that this could even jeopardise the survival of

³³ PFEIFFER J., *La prudenza*, Brescia-Milano, 1999.

humanity and the continuation of life on earth. The synchronic and diachronic expansion of bioethics has increasingly led to extend ethical reflection beyond man (also to animals, plants, the environment, the ecosystem) and expand it beyond the existing (to future, current or remote generations) calling into question biolaw as well, in order to regulate the practice of collective behaviour.

Biolaw has been invested with a task which maybe it was not yet ready for: the accusation that is often aimed at it is one of delay, if not also of absence, when faced with the urgency of bioethical questions in the social sphere. It is not rare that biolegal interventions happen through quick and conditional provisions that at times serve as temporary instruments to halt emergencies, make up any eventual deficiencies, quickly control fears and worries, caused by scientific novelties, but that inevitably hide the need for a more systematic intervention. Moreover, the acceleration of medical and biological technical-scientific progress, constantly poses new problems, contrasts inevitably with the well-known slowness and inflexibility of the law-making mechanisms, amplifying more and more the asynchronicity between techno-science and the law. This is one of the reasons that led to a different biopolitical and biolegal attitude, marked by the intention to speak beforehand about the occurrence of possible negative consequences and characterised by caution when faced with risky situations, with still imprecise outlines, due to the fear that the non-pronouncement can be harmful.

In this sense, in bioethics but especially in biolaw and biopolitics, the appeal to the precautionary principle, which proposes to overcome the economist individualistic logic (conceiving the environment like a property to exploit), has consolidated, going towards an holistic solidarity that stimulates the citizen to become aware of a collective, universal and global ethics, which sees the environment as a good to preserve and maintain for man and its descendants.

At times it happens that the precautionary principle is confused or even identified with Hans Jonas' "responsibility principle". This overlap is incorrect: not all those who support the precautionary principle agree with Jonas' philosophy. Even though it must be undoubtedly recognised that the elaboration of the responsibility principle has in part helped the birth of the precautionary principle (or at least contributed to preparing its acceptance in the bioethical, biolegal and biopolitical sphere). Jonas starts by denying the moral neutrality and indifference of modern technology, highlighting the impossibility of separating the immediate intentional benefits from the involuntary, subsequent harmful effects. The starting point of the responsibility principle is the same as that of the precautionary principle: the awareness of the dangers we are exposed to because of the human technical-scientific power at the cosmic level and the ethical need to assess (teleologically) the risk of the consequences of human actions towards nature. The heuristic of fear, the anticipation of a threat, namely, the uncertainty of the continuity of the human species and the survival of life itself on earth, the question on the destiny of others and the fate of our planet, become the precise object of responsibility, formulated by the imperative: "act so that the consequences of your actions are compatible with the permanence of an authentic human life on earth" or, in a negative sense "act so that the consequences of your actions do not destroy this life's possible future". Jonas stresses how the threat to human identity is one of the main causes prompting the surfacing of an awareness of

the value of safeguarding our anthropological identity (we indirectly recognise the value in light of the non-value we immediately perceive).

It is a theoretical elaboration based on the metaphysics of being (or teleological naturalistic metaphysics, according to which every living individual ontologically tends towards an immanent end that coincides with good), which, starting from the idea that it is better to be rather than not to be (the aim of all aims is life), transfers the categorical imperative (namely, the duty to be) from the individual to the human species: because humanity (present and future) has a right to be respected and to a general ethical protection, as the condition for defending existence, the earth, as human beings' abode, must be safeguarded. Man, being the only creature on earth who has the possibility of choosing between different ends (being able to make choices sacrificing an immediate end for an ulterior end), is called to perceive the objective need of the (human and non-human) being and to guarantee it the achievement of the goal. On this philosophical basis Jonas founds his "macro-ethics" for the technological society: the recognition of the theological structure of the being and the ontological axiom of the superiority of the presence of the aim in comparison to its absence, establish man's obligation to take on the self-affirmation of the being, through the responsibility towards the indigent, a total responsibility, extended to living beings and projected to future generations. The gap between the power of technology and predictive knowledge, between the "utopian promise" of technology and the "apocalyptic threat" of ecology, force us to extend to the environment and posterity, intended as human (and non-human) remote (as well as close) descendants, our duty of responsibility in order to ensure the future integrity of human nature, warding off the eventuality of the planet's destruction. The responsibility of the parents towards their children is the ontogenetic and philosophical archetype of the duty towards entities without a direct relationship of mutuality: the responsibility implies the direct duty of man to "take care" of nature unilaterally.

In this sense Jonas' philosophy stimulated in bioethics the call for an interspecific and intergenerational ethics, reformulating the category of the symmetry (between human rights, where a right claimed by one man can be claimed by any other man in the same situation) and of mutuality (between rights and duties, where exercising a right is guaranteed by the individual's and others' observance and fulfilment of their duties). Symmetry and mutuality are the basis of a moral obligation not only towards those who have rights and duties; these categories must be broadened by defining the principles of responsibility and care that justify the fact that symmetry and mutuality, as well as (spatial) proximity and (temporal) simultaneity, are compulsory. Responsibility means recognising the duty of also taking care of those who are not capable of taking care of themselves, is not able (and never will be) to reciprocate our moral actions (therefore also animals, plants, the environment, future generations); respect means the obligation to protect (with the prohibition to destroy and damage, at least without an adequate reason) also those who are most vulnerable and unable to fend for themselves (therefore non-human beings and inanimate objects), even just on the basis of their aesthetic, symbolic or historical value. It is a "joint responsibility": every man, as a member of a cooperating community (therefore not acting as a single individual) is called to extend his care globally and to increase it in time: every individual is called to answer to others (human and non-human). In this sense

responsibility brings together, it strengthens relational, as well as inter-individual connections, even between species and generations.

In this sense the responsibility and precautionary principle have a semantic value that partly coincides. But if the precautionary principle in some way leads to deferring or regulating a scientific decision (not to abandon it, rather to control it in proportion to the seriousness of the risk) the responsibility principle could, for reasons of care and solidarity, not legitimate certain behaviours, also in the absence of potential risks. According to Jonas, the interest to preserve nature is in itself an absolute moral interest towards which it is legitimate to limit human technological power. If Jonas' philosophy condemns technological power to the point that it suggests an antiscientific and anti-technological abstention, precautionary philosophy does not arrive to such extreme consequences: it does not condemn technological power, but tries to regulate it, limit it, control it (especially with regards to long term effects).

In the context of a philosophical analysis of the precautionary principle, we can say that the contribution of philosophy can be found in having outlined the context and having created the conceptual basis on which this principle and its subsequent use in the law have emerged. Therefore we must not confuse the political-legal dimension (that has explicitly appealed to the principle and has translated it operatively into rules applicable to specific and concrete practices) and the philosophical dimension that has justified the precautionary approach and attitude. We can say that the biopolitical and biolegal dimension of the precautionary principle, although born in the context of the ethics of responsibility, have progressively distanced themselves from it from the point of view of applicative proposals. In other words, if the ethics of responsibility leads towards a strong interpretation of caution, the biolegal precautionary principle (although diversified in its interpretations) represents a weaker version of it. In this sense it would be philosophically wrong to deduce the precautionary principle from the ethics of responsibility: the first leads to practical rules that legitimise behaviours of abstention (also authoritatively imposed) when faced with catastrophic scenarios; on the contrary, precautionary rules discipline the assessment procedures on the risk of the action from an applicative point of view, stimulating science to investigate its knowledge and society to participate democratically to deliberations. If there is a theoretical convergence between the precautionary principle and the responsibility principle, we can say that often there is or there can be a practical divergence. In any case the precautionary principle acts like an anticipation principle (Ewald, 2001).

The precautionary principle outlines the need of an attitude of caution intended as a preventive anticipation of the risk when faced with the epistemological uncertainties of scientific knowledge. The awareness of the relativity of scientific knowledge and the intrinsic inability of science and technology to offer definite results, with the consequent possibility that science is unable to calculate, predict and control the (involuntary negative) consequences of certain applications, and that such negative consequences can cause serious (technically) irreparable damage, leads to the need of giving an ethical basis to the obligation to tackle threats before they happen, on the basis of the duty to anticipate the knowledge or the awareness of the risk when foreseeing potential or eventual future damage, having at our disposal strategies to respond to urgent situations probable in the future (in order to avoid or reduce the risk).

The precautionary philosophy is based on the awareness of the ontological temporal limitation of man and on nature's fragility (present and future) when faced with science and technology, which increasingly manifest their ambiguous status (of growing power on the one hand and structural uncertainty on the other). The precautionary principle is philosophically founded on the awareness of the asymmetry (between man and nature on the one hand and science and technology on the other) and on the commitment to research practical strategies to overcome it in order to recreate the (bioethical and biolegal) conditions to guarantee a symmetric relationship. On the one hand, society feels the need and inevitability of technical-scientific advancement, but on the other it sees in progress a potential threat to man and nature, to human dignity and the protection of the environment.

The precautionary principle therefore coincides generally with an attitude of caution, which intends to avoid on the one hand technical-scientific abstention and on the other its intervention. Grows in bioethics the awareness that any biotechnological experimental intervention on human and non-human beings – and so the introduction of new technologies in the processes of production and management of natural resources – must be preceded by a scientific risk assessment, according to uniform parameters and procedures, and by risk management, namely, by the evaluation of the epidemiological data from an ethico-political and social point of view, in order to put in place the necessary measures if not to prevent, at least to minimise possible damages. Therefore, it is about promoting only those interventions the risks of which (on man, the environment and future generations) have been assessed and controlled, guaranteeing the safety of the laboratories, the balance of the ecosystem, the control and minimisation of the harm for other organisms, seeking the good for today's society, avoiding possible negative effects for the society of the future. The objective must be to optimise the risk, that is, to contain the damage in proportion to the social benefits that can be obtained for the protection of human life and health, for the safeguard of the existing and not yet existing human community.

Precautionary philosophy is therefore not a global utopia, but a concrete way to answer the needs and threats to man and the environment, with the precise aim of fixing the limits of the power (the decisions of the researchers, scientists, experts, in public policies and individual deliberations), as long as such decisions can affect (human and non-human) life and health. The precautionary principle is therefore a biolegal instrument of regulation, but also indispensable to creating the conditions of social acceptability of the risk, opening scientific controversies to public debate, favouring social cooperation and the democratic participation to the public discussion on scientific problems and demanding transparency in the communication between science and society.

CHAPTER III

Legal aspects of precaution

1. Introduction

As already mentioned in the previous chapters, the contrast between potential benefits, potential risks and the harmful effects deriving from the progress of science and technology, which can be found at every stage of the evolution of human activity, has appeared as obvious as ever in these last few years, on the basis on the ongoing consolidation of trends of socio-economic and technological development, susceptible not only of damaging the human habitat, but also of altering the ecological balance of the entire planet. Even disregarding well defined catastrophic events, we cannot avoid recalling, with regards to this, more relevant critical phenomena linked to the abovementioned trends, like the reduction of the ozone layer, the raising the earth's temperature deriving from the so-called greenhouse effect, the progressive desertification of vast areas, the impoverishment of the biological diversity (so-called biodiversity), the destruction of entire ecosystems.

Together with these "global" environmental risks, specific relevance has the food and health crisis that has considerably affected the conditions of public health protection (infected blood, mad cow, dioxin in chickens, hormones in meat). As widely stated, the appearance of these risks has produced a dual order of consequences, initiating, on the one hand, a new perception of the relationship between man and nature, based on the awareness that economic and technological progress cannot happen at the expense of environmental health, and highlighting, on the other hand, the inadequacy of purely reactive protective interventions and of improbable restorations.

Of particular significance on the perspective mentioned seems, for example, the comparison between the 1977 United Nations General Assembly Resolution n. 32/50 and the 1988 Council of Europe Parliamentary Assembly Resolution n. 1068, both regarding the use of nuclear energy. Whilst the first stressed the importance of this source of energy for the economic and social development of mankind, the second (adopted following the tragic Chernobyl incident) defined nuclear energy as "potentially dangerous" and recommended, a little more than ten years after the ONU Resolution, a moratorium on the construction of new nuclear power stations. Just as significant seems the attitude taken by the international Community with regards to the problem of climate change, seen as, still in 1961, the United Nations National Assembly recommended member states to promote the development of atmospheric science and technology in order to perfect the knowledge of the fundamental physical forces that would have allowed, amongst other things, "changes in large scale meteorological conditions".

Instead, the preoccupation regarding climate change is evident in the United Nations Framework Convention, signed in Rio de Janeiro in June 1992, the Premise to which states that "change in the earth's climate and its adverse effects are a common concern of mankind".

To the increased awareness of the consequences that modern human activities can produce, in terms of serious and irreversible damages to the environment and human health, corresponds a gradual increase in the need to favour preventive actions and cautious approaches, able to eliminate at the

root, as much as possible, of the foreseen risks. It is on the basis of these solicitations that the “precautionary method”, although not new as a theory or as a practical approach, encountered in recent times the renewed interest of those studying and working within the law. We can instead state that the re-evaluation of this method through the definition of a “precautionary principle” has been such to motivate (rectius, insist on) the expansion of the principle’s field of action also to new and different issues from those first elaborated, relative, as is known, to the protection of the environment.

And, in truth, talking about the precautionary method today usually means referring to a line of action, in the field of political and regulatory decisions, concerning the management of scientific uncertainty on the probability that, in the long term, certain risky events would actually happen, both with regards to the protection of the environment and natural resources, and the protection of human health. From this point of view, and with specific reference to the outlook in biomedicine, it is important to remember that Recommendation No. (2003)10 of the Committee of Ministers of the Council of Europe, adopted on the 19th of June 2003, repealed the moratorium on xenotransplants (transplants in humans of genetically modified organs, tissues or cells of animal origin for therapeutic purposes), which the same Council of Europe had previously adopted, with Recommendation No.1399 (1999). With the new Recommendation, the Council of Europe gave some indications and guidelines inspired to the precautionary method in relation to the possible risks of spreading to humans known or unknown illnesses or infections. In particular, the Council of Europe invited member states to adopt the appropriate measures, in conformity with proportionality and necessity principles, to monitor the health conditions of the so-called receiving subjects, in order to responsibly answer eventual adverse reactions. This is a particular point of view, directly linked to the protection of the dignity and integrity of the human being with regards to biomedicine applications, which however clearly shows in which sectors the precautionary principle will be mostly used in the future, in consideration progress in the field of the so-called life sciences (think, finally, about the interaction between genetics and informatics in the so-called nanotechnology sector).

2. The origins of the “precautionary principle” in international and European Community law

Brought into play initially in marine environmental protection, the precautionary principle appeared first of all in the Ministerial North Sea Conferences, presided over by the Organisation for Cooperation and Economic Development (OCED) in 1984. But it is in the 1992 Earth Summit, in Rio de Janeiro, that the principle under examination was universally recognised in the field of environmental protection, with the following formula: “in order to protect the environment, the precautionary approach shall be widely applied by the States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be the used as a reason for postponing cost-effective measures, to prevent environmental degradation”. The United Nations Conference on Environment and Development (UNCED), in fact, adopted a series of Recommendations with which the states participating in the Summit took the commitment to promote an economic and social development compatible with the need to safeguard the

environment. In particular, the Rio Declaration on Environment and Development, in its twenty-seven general principles, sanctioned the absolute need for development and environmental protection to be compatible, according to a criterion of “sustainable development” at the basis of the international cooperation of the protection of the environment since the well-known 1972 Stockholm Declaration. In order to realise a development model, the Rio Declaration formally included the “precautionary principle”, used beforehand in many international Recommendations and conventions, amongst the general principles on which to base national environmental policies. The Rio Convention on Biological Diversity also confirms the application of the precautionary method in relation to the need to protect environmental and natural resources, with particular reference to the adverse effects of the loss of the so-called biodiversity.

Following the Rio Conference, the precautionary principle (almost always together with the principle of sustainable development) was received in the modifications made to a large number of pre-existing conventions as well as in a series of agreements relative to the management of natural resources and environmental protection, both universally and regionally. In particular, in the context of the so-called Multilateral Environmental Agreements, particular importance for the purposes of this document has the Cartagena Protocol on Biosafety, additional to the Rio Convention on Biological Diversity and in force since 2003, which disciplines the trans-border movement of modified living organisms, anticipating the recourse to risk assessment procedures aimed at ensuring, on the one hand, the preservation and sustainable use of biological diversity and, on the other, the preservation of human health, “in accordance with the precautionary approach” and in the sense of recognising the right of the participating states to ban the import into their territory of modified living organisms.

In European Community law, the precautionary principle finds its first recognition in some rulings by the Court of Justice adopted since the 1980s, in relation to cases of restrictive measures on European Community trade based on uncertain scientific knowledge.

It is, however, a small legal acquis, not devoid of contradictions and only in 1993, due to the modifications made to the Treaty of Rome by the Maastricht Treaty, the precautionary principle has had a formal recognition within European Community policies on the environment. The modifications introduced reinforced the statement in principle and the substantive directives relative to the environmental policy contained in the Treaty establishing the European Community, favouring the integration of assessment and ideas regarding economic development in the context of the principles applicable to the protection of the environment, in line with the experience matured internationally. From this point of view, the new directives explicitly link, on the one hand, to the “sustainability” of economic growth amongst the objectives assigned to the European Community by Article 2 of the Treaty of Rome and to the European Union by Article 2 of the Maastricht Treaty, and, on the other, the “precautionary principle” amongst the founding principles of the environmental policy of the European Community, without however defining characteristics and premises to apply such a principle. This was done by the European Commission on the 2nd of February 2000, which, without giving a formal definition of the precautionary principle, attributes to it a very wide field of applications. Since then, the precautionary principle has quickly become part of

all the policies of the European Community, the basis of which is the clarification of the risks inherent to technical-scientific development. With regards to human health, for example, the focus of European Community institutions and bodies on the precautionary principle is such that a document by the European Environment Agency published in 2001, aimed at linking the premises of this principle to a series of case studies going back to the XIX century (cf. Late lessons from Early Warnings: the Precautionary Principle 1896-2000, Luxembourg, 2001).

Emblematic example of an application of the precautionary principle in the European Community is offered by the legislation regarding the limited use, the deliberate release in the environment and the introduction on the market of genetically modified organisms and the products (especially food) made up of, containing or obtained with these organisms. This legislation is inspired to the “strong” version of the principle under examination, because it disciplines a procedure of advanced authorisation for carrying out activities based on the overturning of the probationary duty regarding the scientific evidence of the harmlessness or harmfulness of certain products (or production processes): in other words, whilst the responsibility to demonstrate the nature of a danger and the level of risk associated to a product (or to a procedure) is generally given to the consumer or the public authorities, European Community directives on GM food transfer to the subject intending to carry out a certain activity the responsibility of providing scientific proof of the products’ harmlessness (or of the safety of the procedures in question). This means that certain substances (not only GM food: from antiparasitics to medicines, only to give some examples) must be considered potentially dangerous, at least until it is not possible to prove the contrary with enough certainty. And it is useful to observe that said “radical” interpretation of the precautionary method, also accepted by many international organisations of environmental law, gives rise to the most heated discussions on its practical scope.

3. The European Commission Communication of the 2nd of February 2000

In order to identify the situations in which the precautionary principle can be called upon and to define effective guidelines for the application of such principle, the European Commission adopted, on the 2nd of February 2000, a Communication in this regard (cf. Document COM(2000) 1 of the 2nd of February 2000). Although it does not give a formal definition of the principle, the communication indicates the conditions in which it is possible to bring it into play: a scientific assessment has occurred, such assessment has identified the lack or deficiency of available data (or the differences with regards to their interpretation in the scientific community) and there are sufficient reasons to believe that from the assessed phenomenon (or product, or procedure) could derive potentially dangerous effects for human, animal or plant health, or the environment. According to the Commission, therefore, the field of application of the precautionary principle is very broad, so that it can be applied, in practice, in all those circumstances in which scientific proof is insufficient, inconclusive or uncertain and there are reasonable grounds to fear that the risks for the environment and human (but also animal and plant) health are incompatible with the level of protection chosen by the European Community.

Defined in this way, the conditions of application and the scope of the precautionary principle is called to carry out a structured strategy of risk analysis, comprising of the risk assessment, risk management and risk communication phases. With regards to this, the Commission highlights first of all the dishomogeneity of opinions that exists about the importance to be given to “scientific uncertainty”, which derives from the confusion created by the prudential approach, which scientists use in the phases of analysis and evaluation of scientific data, and the precautionary method, which must find its application in the risk management phase. According to the Commission, therefore, where the condition of scientific uncertainty does not make it possible to completely assess the much-feared risks (and, consequently, the possibility that damage can actually take place), it is the politicians’ duty, on the basis of the precautionary principle, to identify what is the minimum level of “acceptable risk” for society. And it is in this assessment that, according to the Commission, the principle under examination comes into being: politicians, faced with scientific uncertainty, an indefinable risk and public opinion’s preoccupations, have the duty to give answers, taking into account that the “precautionary” aspect goes beyond the temporal horizon of short or medium term, to invest issues the scope of which can be found in the long-term, and it concerns the well-being of future generations.

We must not however believe that the application of the precautionary method, so intended, legitimises arbitrary decisions. In the European Community, in fact, the precautionary principle prefigures general rules for the management of potential and uncertain risks, aimed at becoming, case by case and in effect, norms of behaviour valid both for the public authority and for economists, as well as for techniques and instruments of social action aimed at communicating and sharing the risks linked to technological development. In other words, the precautionary principle allows us to go from a generic disposition to caution and care in identifying a route, even with regards to procedure, which public authorities must follow in situations of uncertainty.

After all, the European Community Court of Justice has taken steps to stress the premises for the application of the precautionary principle, ensuring at the same time its role of parameter for the legitimacy of the deriving acts of European Community law. In fact, in a number of rulings the Court confirmed, on the one hand, that scientific uncertainty is the essential premise for the application of the principle and, on the other, that the precautionary method refers to the long-term consequences and inaction can cause irreparable damage. Leading case of the Court of Justice legislation is the contentious caused by the adoption, by the European Community, of restrictive measures against the export of beef from the United Kingdom in order to limit, in this way, the risk of spreading bovine spongiform encephalopathy (so-called mad cow disease or BSE). In this as in other cases, in fact, the Court established, talking to other European Community institutions, that “where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent”.

In order to follow the affirmation of the precautionary principle with action, the communication finally indicates the guidelines destined to overlook the choices politicians are called to make. According to the Commission, the precautionary principle must not necessarily be translated in the adoption of directives aimed at producing legal action and susceptible to the control of the

law. In some cases, in fact, the most appropriate solution can be the adoption of directives that are not legally binding, like Recommendations, or the recourse to a wide variety of “political” actions, like funding research programmes or the decision to inform public opinion of the possible adverse effects of a product or procedure. In other cases, instead, the adoption of adequate protective or preventive measures can be necessary, which should be inspired to the general principles and criteria indicated in the communication under examination. They are, as stressed by the Commission, criteria that can be applied with reference not only to the precautionary principle, but to any risk management measures and that require the recourse to democratic and transparent decision-making procedures. In particular, the principles recalled by the communication should allow the adoption of decisions proportionate to the chosen level of protection, not discriminatory in the application of the measures that have been set up, coherent with the measures already adopted in similar circumstances, subjected to revision on the basis of the evolution of scientific knowledge and based on a comparative analysis, also economic, of the advantages and duties deriving from the chosen action or inaction (cost-benefits analysis). Therefore, precautionary measures should be: Proportional: measures must be proportionate to the chosen level of protection; Fair: measures must be similar in similar situation and different in different situations, unless there are objective reasons to behave otherwise; Coherent: measures must be of a strength and nature comparable to those already adopted in similar areas, in which all scientific data are available; Based on an assessment of the potential advantages and duties: measures must come from the comparison between the general costs for the collective of the action or the inaction and their acceptability by the public. In any case, the protection of health must come before economic considerations; Subjected to revision: precautionary measures must be maintained for as long as scientific information is incomplete, and they must be revised in the light of new data; Able to attribute the responsibility for giving scientific proof: where is in force the “upon approval” requirement on the products under consideration, we anticipate overturning the duty of proof – so that it is the economists’ duty to prove the product’s safety; otherwise, the duty of proof can be allocated to the users or public authorities, however this cannot be a general rule.

On the basis of the trends we have examined, European Community institutions widely use the precautionary principle. The Commission called upon the principle under examination first of all to assess national measures restricting the marketing and use of certain products, also in light of European Community regulations for unilateral dispensations to directives aimed at harmonising the functioning of the domestic market. From the relevant practice emerges the Commission’s stance, aimed at denying authorisation for national measures of dispensation based on the generic appeal to certain dangers, but devoid of specific demonstration, and to acknowledge unilateral restrictions based on completely verified scientific data, confirming in this sense the need to have scientific evidence that is able to prove the rationality and objectivity of the much-feared risks.

Subsequently, working with the clear formulation of the precautionary principle, the law has been more favourable to generally recognise the premise of scientific evaluation, and therefore also towards European Community institutions. So, even when it is not plainly mentioned, the precautionary principle can be seen between the lines in many rulings made by the Court of

Justice to evaluate the compatibility of national directives and European Community law or to question the legitimacy of European Community measures. This jurisprudence has particular importance because, on the one hand, legitimises health protection measures, broadening the field of material applications of the precautionary principle and, on the other, justifies the adoption of measures restricting the free circulation of goods. Think, from this point of view, to the Court's statements, also recalled in the Commission's Communication discussed above, according to which "in the absence of harmonisation in Community rules, member states must decide what degree of protection they intend to ensure to public health", as well as the means to achieve such protection, taking in any case into account that "the needs linked to the protection of public health should undoubtedly be given greater weight than economic considerations".

In the current state of development of European Community law, therefore, we can say that the Court of Justice aimed at excluding, on the one hand, any application that potentially abuses the precautionary principle (those, for example, masking restrictions to exchanges or commercial barriers), and, on the other, the "minimalist" versions of this principle, susceptible to reducing the useful effect. It is a trend that puts the precautionary principle at the heart of an evolutionary process that marks the passage from a model of legal control of logical-formal legality to a teleological model, aimed at finding more adequate solutions to the concrete case in function of the objective pursued case by case by the legislator.

However, it is true that the Court has never expressly approved the precautionary principle as a general principle of European law, whilst some legal acts show a tendency to a progressive consolidation of the precautionary principle (like for example the regulation that institutes the European Food Safety Authority), which is now hoping (although it might not be able to) become an independent legal regulation, but not without falling again into domestic law.

For the purposes of the future consolidation of the precautionary principle in the European Community, particular importance has the political support given to the Commission's communication by other European Community bodies and, particularly, by the Resolution on the precautionary principle adopted by the European Council that took place in Nice from the 7th to the 9th of December 2000. This Resolution invites first of all the Commission to systematically apply the guidelines issued in its communication in every sector of future European Community activity, developing, together with the member states, the most appropriate initiatives to support the international recognition of the principle under investigation. The European Council Resolution highlights, in addition, the responsibility of public authorities to guarantee European citizens the most complete information with regards to the scientific knowledge and the risks affecting the environment and the human habitat, ensuring at the same time the level of health and environmental protection believed to be most appropriate. In this sense we can say that the Resolution highlights the autonomy of the political power towards scientific expertise, especially when decision-making authorities, to which the precautionary principle is mostly aimed, are faced with fears or solicitations coming from the public about irrational or scientifically unproven risks. The European Council Resolution, finally, hopes for a more explicit development of European Community law with regards to precaution, stating, in line with the Court's law, the need to formally

define the principle under examination and other directives of the Treaty of Rome.

4. The international scope of the precautionary principle

Very different is the interpretation of the precautionary principle given by the World Trade Organisation (WTO). In the framework of the multilateral trade agreements administered by the WTO, operating the difficult attempt to merge the application of the principle of free exchange with the safeguard of the need to protect the environment and human, animal or plant health, the principle under examination did not have, in fact, the same ability to infiltrate. Placing itself in the fracture between the assumption at the basis of the liberalisation of exchange and the need to ensure a high level of environmental or health protection, it is instead in the context of international trade law that the precautionary principle fights a battle for survival.

It is easy to observe, with regards to this, that the level of environmental, health or consumer protection varies considerably from one state to the next (we only need to think about the “hormones in meat”, freely sold in the United States and contested in Europe) and that the measures of one state nominally aimed at ensuring certain levels of environmental or health safety can appear, in the eyes of the less “prudent” states, as discriminatory or protectionist measures, aimed at hiding unilateral restrictions to business exchanges. Within the WTO, therefore, exercising the right of member states to adopt policies aimed at the protection of the environment and human life or health intertwines and must come to terms with an objective, the liberalisation of business exchanges, which in some cases can seem to be in conflict with the protection of more general interests.

It is for this reason that, within the WTO, the 1994 Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) implies the reference to the precautionary principle where it recognises the right of the participating states, where “the relevant scientific evidence is insufficient”, to adopt temporary measures of sanitary or phytosanitary protection on the basis of the simple “available pertinent information”. In this way, the SPS Agreement clearly expresses the need to ensure a scientific foundation of sanitary and phytosanitary measures able to limit business exchanges, overturning the approach at the basis of the precautionary principle found in international law regarding the environment and in European Community law, according to which, in case of doubt concerning the harmfulness of a product (or a procedure), the protection of the environment or human health should prevail on any other need (and specifically on economic interests. In other words, in the system of the SPS Agreement, the legitimacy of the measures of sanitary and phytosanitary protection finds its basis not on scientific uncertainty about the existence of risk, but on the definite harmfulness of a product³⁴. It is also significant to observe that, whilst the SPS Agreement refers to “provisional”

³⁴ Cf. Art. 5, paragraph 7 of the SPS Agreement, according to which “in cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organisations as well as from sanitary and phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review of sanitary and phytosanitary measure accordingly within a reasonable period of time”.

measures, the Commission's Communication does not give temporal limitations to the duration of the precautionary measures created. It is true that the adoption of such measures involves, according to the Commission, the duty to investigate the scientific knowledge on the issue, in order to overcome the situation of uncertainty, but the communication requires not an explicit declaration of time for the measures in question, but a regular scientific check on them (so-called monitoring), which allows a new assessment of the measures adopted in light of the new information obtained. So, as stated by the Commission, the temporary nature of the precautionary measures is not linked to a mere temporal factor, but to the evolution of scientific knowledge.

From this point of view, it is possible to identify one of the most relevant differences between the interpretations of the precautionary principle adopted by European Community institutions and that adopted by the WTO, which reflect the contrast existing on this issue in the different European Countries (which however have very different points of view) on the one hand, and United States of America on the other. And the differences seems destined to translate in litigations, as demonstrated by the fact that the United States contested the recent European Community regulation on the labelling and traceability of genetically modified products (which in effect allows the citizens to decide whether they want to buy certain products or not), on the premise that this regulation gives American manufacturers and exporters excessive responsibilities, as it is essentially aimed at limiting business exchanges with Europe.

5. The effects of the precautionary principle on Italian Law

The precautionary principle has not yet been openly received in national legislation, where there isn't a general rule that, on the example of art. 1 of the French Code de l'environnement – according to which “the absence of certainty, based on current scientific and technical knowledge, must not delay the adoption of effective and proportionate measures aiming to prevent a risk of serious and irreversible damage to the environment at an economically acceptable cost” –, defines such principle.

This does not mean, however, that the problems linked with it have not been felt. We can therefore talk about precaution as a need that deserves protection rather than of a defined legal principle.

This explains the confused and sometimes conflicting approach to the relative operative solutions.

See, with regards to this, some classic examples that have in common the extension of the need of precaution from the protection of the environment to the safeguard of health.

A standard example of conflict occurred on occasion of a regional law (Regional Law Marche, 13th November 2001, No. 282) which, calling upon a precautionary need, ordered the interruption on all the regional territory of electroconvulsive therapy, raising an issue of constitutional legitimacy which ended up in being deemed unconstitutional (Constitutional Court 26th of June 2002, No. 282), in which the Constitutional Court, without openly naming the precautionary principle, stated that, according to art. 117, subsection 3, Constitution, “the fundamental principles are laid down in State legislation” and, in any case, they could not come “from purely discretionary assessments of policy by the legislator”, but should “anticipate the creation of trends founded on

the assessment of the state of scientific knowledge or acquired experimental evidence, by institutions and bodies – usually national or supranational – entrusted with this task”.

In another case, which asserted the “almost certainty of the biological consequences of electrical and magnetic fields” induced a judge to order “the movement of electro-ducts if easy to carry out” (Milan Court, 7th of October 1999), Cassation Court – which had subsequently stated in general terms the judges’ obligation to not refuse to “ascertain if the right to health of those exposed to the danger of being compromised by being exposed to an electro-duct magnetic field” (cassation, 27th of July 2000, n. 9893) – was shortly after deprived of authority in its natural nomophylactic function by the intervention of the national legislator, who issued a “framework law on the protection from being exposed to electric, magnetic and electromagnetic fields” (Law No. 36, 22nd of February 2001): a law that raised contrasting reactions between those who saw favourably the end of the autonomy of the legal power on this issue³⁵ and those who highlighted the fact that the precautionary limit established by the law is arbitrary, so that, paradoxically, “below the threshold, by legal definition, electromagnetic waves would not be harmful, or in any case they would not be with regards to possible legal consequences”.³⁶

The mixed fortune of “genetically modified organisms” (GMO) is, finally, characterised by a variety of regional laws that, although motivated by “an indisputable unity of intent” for the protection of the environment and of health, are “incoherent, full of gaps and contradictory”, and especially “demonstrate serious defects in systematic coordination” often showing that they “ignore the existence of national and European legal sources that for the protection of health and the environment have disciplined the release into the environment and the introduction on the market of GMOs”³⁷.

The doctrine has still not initiated a process of critical reinterpretation and reconsideration of the existing norms, in the open perspective of the precautionary need, mostly preferring to entrench itself in a sterile juxtaposition between those who believe in “a precautionary principle applied according to the zero risk criterion”³⁸ and Italian sympathisers of the known definition of the precautionary principle as “a wolf in sheep’s clothing”³⁹.

But a similar process cannot now be given up, seen as the need for precaution, if it still cannot be defined a principle of national law, is without a doubt an essential hermeneutic criterion founded on European Community law, which will act in particular on the issue of civic responsibility.

With regards to this, two significant examples can be mentioned.

Art. 2050 of the Italian Civil Code, which with a “far-sighted” regulation (for the time – 1924 – in which it was formulated) and innovative compared to the main codes in effect in Europe at that time, anticipates an inversion of the duty

³⁵ CONSOLO C., *Il rischio da ignoto tecnologico: un campo arduo per la tutela cautelare (seppur solo) inhibitoria*, in *Il rischio da ignoto tecnologico*, Acts of the XIII seminar of the quarterly Journal of Civil Law and Procedure, in process of publication.

³⁶ MERUSI F., *Dal fatto incerto alla precauzione: la legge sull’elettrosmog*, in “Foro amministrativo”, 2001, p.223.

³⁷ GALASSO G., *Il principio di precauzione nella disciplina degli OGM*, ed. provv., Giappichelli, Torino, p. 178 and following.

³⁸ CORRADINI H. BROUSSARD D., *Il “principio di precauzione” e il problema della brevettabilità*, in process of publication.

³⁹ POLLAN M., *Precautionary Principle*, in “The New York Times”, 9th of December 2001.

of proof with regards to “responsibility for exercising dangerous activities” could be extended, in a precautionary perspective, to exercising “only dangerous” activities, if we agree with the premise that “the protection of the right to health must in these cases prevail compared to the freedom of economic initiative”⁴⁰.

The same point of view could lead to critically reconsider – also in view of an eventual legal modification – the norm that, when carrying out European Community Directives “on the liability for the damage due to dangerous products” (85/374/EEC, art. 7, letter e), stated the exclusion of responsibility “if the state of scientific and technical knowledge, at the moment in which the manufacturer put the product into circulation, was not such as to enable the product to be clearly considered as contemplated in the abovementioned Directive (art. 15, letter h) and so causing since then the fierce criticism of the most authoritative commentators⁴¹.

In conclusion, Italian law has not yet made official the introduction in the national system of the precautionary principle; but the system cannot ignore the need implied by it, and it is called to rationalise the protective measures for the environment and health that are direct expression of it, involving with distinctive roles the (national and regional) legislator, (constitutional, civil, administrative) jurisprudence and policy: from which, in particular, we expect a systematic reconstruction of the current legislation, which takes into account an hermeneutic criterion founded (if not on the principle, certainly) on the need of precaution solicited, or imposed, by European Community law, and by European Constitutional law, as can be seen by the European Union Charter for Fundamental Rights (so-called Nice Charter), which recommends “a high level of protection” for human health (art. 35) and for the environment (art. 37).

⁴⁰ PIZZORUSSO A., *Il patrimonio costituzionale europeo*, Zanichelli, Bologna, 2002, p. 68 and following.

⁴¹ PARDOLESI R., PONZANELLI G. (ed.), *Commentario*, in “Le nuove leggi civili commentate”, 1989, p. 565 and following.

CHAPTER IV

Synthesis and conclusions: public opinion and the political responsibility in risk management for the social acceptability of it (costs/benefits assessment) and application of the precautionary principle

What has been said so far is already more than enough to outline the role of the “precautionary principle” in today’s society. We think it appropriate – going towards the conclusion – to present the following summative reflections:

1. In the trend prevalent in today’s society, it is hoped for each individual to take on their responsibility for appropriate ecological and lifestyle choices, as they are in line with their most genuine interests.

In this sense, the knowledge and quantification of the environmental risks that can be controlled by the individual, or by small communities, promoted by communication agencies with appropriate and convincing methods – should lead to feeling that many risks of this type (for example pollution from agricultural or city refuse, etc.) not as unchangeable fatalities, but as removable or at least diminishable dangers, by simply using criteria of appropriateness and caution in the actions of every citizen.

This involves great a dedication to education in order to harmonise the State’s institutional duties with committed initiatives of protection also to reassure the public.

A constant action of information and formation of the individual, starting at school age, for the correct management of the environment and of the methods relating to it, is the first duty of political and administrative activity.

2. Beyond the common and widespread source of risk “manageable” by the individual, there are problems of generalised risks on which we exercise – traditionally – control and the responsibility of public administrators and Governments with a series of interventions of various nature, not only linked to the classical instruments of civil and penal law, but also to “principles” that seemed – with experience – more suitable to manage human activities on the environment and territory. For instance, the user/payer principle; the polluter/payer principle (in general applicable for low risk activities), the mitigation principle; the prevention principle and finally the “precautionary principle”.

If the main responsibility to manage generalised risks belongs in any case to public administrators, today the situation is much more complex compared to the past, amongst three actors: the decision-maker, the expert, the citizen (who appears in the dual role of economic producer and consumer) and it is characterised by the fact that – at least for a long time (and in some cases still today) – the consumer has been kept in the dark about decisions that can affect the safety and health of the environment in which he/she lives and with regards to his/her health, and this can no longer be acceptable.

We can state – globally – that whilst the doubt of the public towards the reliability of “expert” opinion has increased (as documented before), the participation of public opinion to the non-“scientific” analysis of the problems and its importance in the decision-making process has also increased.

In this sense, we can say that the main objective of the “precautionary principle” is that of forcing the decision-maker to explain, quantifying them, his/her objectives and to inform in the most objective way possible. In the framework of political decision-making this poses the problem of exercising democracy, because it is a way of managing risk that it is also a rethink of public ethics, economy and social protection.

For these reasons, the demand for “transparency” has also increased, forcefully presented to the public administration by citizens’ conscious of being “consumers” often unaware of even the indispensable manufacturing processes, as in food.

Labelling – introduced by the European Community – answers these needs and documents the application of a “principle of respect of the informed choices made by the consumer”, the introduction and dissemination of which in business regulations is more and more supported also by the national political power. A significant example is the recent European Community legislation concerning genetically modified food and animal feed.

3. The change relative to the treatment of environmental and health risks has been the object of detailed evaluation by the European Community which, following the Communication on the precautionary principle (see chapter III), issued many directives aimed at highlighting the widespread and constant need for European citizens’ participation to the management of the programmes concerning the applications of research activities that have industrial effects. The reflection of the European Community, if aimed at giving responsibility to the government, must make sure that the population is not considered a passive object, the interests of which have to be looked after, in a paternalistic manner, only by experts or scientists.

We can therefore conclude stating that the precautionary principle, as identified in the European Community, has highlighted new ways to interact between citizens, scientific expertise and public powers through the continuous and constant adaptation of decision-making processes, also reinforcing a democratic participation to the creation of the regulations.

The distinction between pure and applied science must be increasingly evident in public management with regards to the precautionary principle: applied science cannot forgo the assessment of the risks linked and resulting from large scale experimentation on the environment. From this point of view it becomes a duty for the government to behave responsibly towards the prevention and at times the application of the precautionary principle, in conditions of scientific uncertainty.

Already in the White Book on European Governance (European Commission, 2001) the Commission launched a programme aimed at carrying out the reform of the European governance defined as “the way in which the Union uses the powers given to it by its citizens”. The document clarifies the regulations, procedures and behaviours within the competences and they are identified as “principles of good governance”, those of openness, participation, responsibility, principles that must be applied at all levels of government, European, national, regional or local.

Also in the Commission’s VI Framework Programme of Research and Development (2002-2006) public participation in environmental issues is encouraged and the difficulty, in the absence of a general and continuous commitment of society overall, of achieving the results. The seventh Priority

Area of the Programme is clearly dedicated to “Citizens and Governance in a Knowledge-based Society”.

4. The notions of the scientific assessment and scientific uncertainty of human activities, especially industrial ones, have been discussed in detail in the last few years both in America and Europe, both in society and by the political power.

Also the reflection carried out in Europe on the application of science in conditions of uncertainty has highlighted a dual need: the first regards the democratization of scientific expertise (which must be increasingly open, able to include minority or dissenting scientific opinions); the second one concerns, instead, the need for correct and transparent information aimed at including, if possible, the participation of society to the decision concerning it. Scientists and experts should not be the only ones qualified to make ethical decisions that are at the basis of civil and social transformations and that can involve risks able to harm the fundamental right of man like the right to health and a healthy environment.

Already the Council of Europe in Nice, in December 2000, stated the need for public authority to take on risk organisation and assessment guaranteeing a plurality of perspectives, independence and transparency: in addition, minority opinions must be presented in “expertise” documents, where they highlight the lack of adequate scientific research (pp. 9 and 10) as it is necessary. . . “that society must be involved and that all interested parties are involved, as much as possible from the earliest phases (European Council 2000 p. n. 15)”.

Of particular interest is the Plan of Action on Science and Society (European Commission 2001) where the strong interrelation between science, technological innovation and social change are stressed and where the objectives and actions for the promotion of European scientific culture and the development of a research that is closer to the public, is indicated. The document, talking about a responsible science at the basis of scientific progress, highlights that “science is often perceived as dealing with certainty and hard fact; whereas in reality this is rarely the case, particularly at the frontier of research” (Action 35, point 3.3). This would make a more open approach, systematic in nationally and in Europe, necessary to identify the most adequate competences, opening to public consultation procedures and to the interested parties at the right time, giving them opportunities and tools to allow them to contribute to the debate and to contest the experts or their opinions. Moreover, it is quite surprising that governments continue to promise “certainties”, when the symbolic universe of today’s society is increasingly more imbued by “risks” and “uncertainties”.

5. For the decision-making power, in light of these trends, but faced with the paradigm of “sustainable development”, there is the need on the one hand to simplify and rationalise the procedures – on the other to have more cautious authorisations and in effect to be of more assistance and have more control of the management of human activities dangerous for the environment and health, recurring to the by now differentiated legal tools available today. Amongst them, also the “precautionary principle”, the use of which should be reserved to governments (in line with European Community legislation and – for Italy – with what is indicated in the reformed art. 117 of the Constitution), finding also a more accurate legalisation.

6. In general, the precautionary principle was accepted favourably by public opinion, and it has been called upon as new episodes of not sufficiently prevented risks have appeared in human activities.

Also information and the investigation of the principle's meaning have progressed.

The focus of some very prestigious journals has been in many occasions aimed at the problems of risk, prevention and precaution in different European Countries, and many are by now the doctrinal elaborations regarding both the "expert" and the scientific reflection and inherent to the role of public opinion and the tasks it gives to politicians. It is growing both in culture and in public opinion, the awareness that a generic appeal to "responsibility" is no longer enough, a term that has also become full of ambiguities and mental reservations, but what are needed is precise commitments and actions, on the basis of clearer and diriment principles.

Much of the most recent literature regarding the application of the "precautionary principle" mentions not only the by now "classical" risks of nuclear and industrial plants, but especially of those many forms of interest in food (for example GM foods and the polluting agents of industrialised agriculture) of the possible risks on the biology of living beings caused by other pollutants (consider for example electromagnetic energy, etc.) or other by now appreciated environmental risks for human health, which – although in the presence of a variety of opinions – still require a more decisive scientific assessment.

To strengthen this favourable response of public opinion, it is not devoid of meaning the fact that the European Community Court of Justice, with the ruling of the 21st of March 2000, interpreted Council's Directive n. 90/220 of the 23rd of April 1990, relative to the deliberate release into the environment of GM foods, in the sense that it allowed the States to deny their consent to the release on condition that there are sufficient scientific data able to prove that the product, object of the notification, can be dangerous for the environment and human health. In any case, the State in question must inform without delay the Commission and the other Member states to start the European Community procedure disciplined by directive n. 90/220⁴².

7. Some researchers have seriously doubted the "legal value" of the "precautionary principle", at least from a point of view of positive law, although they do not deny its value of "tendency" especially in those phases in which administrative authority (at various levels for some, only "centrally" and for national decisions for others) must apply positive and statutory regulations⁴³.

It is certainly necessary to stay away from any unmotivated recourse to the precautionary principle, as zealous supporters would like to impose it wherever they can.

We must instead give a reasonable explanation of this principle, which will have to be rigorously applied only when a specific risk is identified (although not yet exactly estimated) by the community of experts.

It is also true that it is the task of the Community of citizens – in the heterogeneous composition of different and at times contrasting interests that characterises it – to establish what level of safety it wants, also at the cost of

⁴² Cf. *Greenpeace's ruling*, in "Environmental Legal Journal", 2000, p. 457 and following.

⁴³ GROS M.; DEMARBE D, *La controverse du principe de precaution*, "Revue du Droit public", 118/3, 2002, pp. 821-845.

giving up economic development, and it is just as true that – also in the European Community – the considerations regarding the protection of health have precedence on economic and business ones. However, in the European Community – is in force the application of the general principle of proportionality, which must harmonise with that of precaution.

8. Looking to the future, there is much to do at the level of information and formation of conscience (awareness and motivation) on the objectives and methods to ensure the protection of the environment and the health of the living, in the framework of a truly sustainable development.

Amongst the development tools (and not only “defensive”) we must also list the “precautionary principle”.

We are, in any case, in a moment of transition about the scope of the legal efficacy of such a tool.

It must be recognised that the precautionary principle is exercising a profound influence on the legislation of risks producing – in some sectors – two legislations with distinct and sometimes contradictory objectives. The objective of the first is that of reducing the exposition to old risks, of the other that of stopping the changes in technology that could lead to new risks for our lives, without completely eliminating the previous ones, although diminishing their importance.

In any case, the “precautionary principle” must be applied wisely, without forgetting that it should be a regulation limited in time, suspended, waiting for scientific clarification. The objective to pursue, in fact, is that of bringing back the trust between politicians, administrators, technicians and citizens, in the awareness that trust is an important resource, fundamental in complex societies.

9. Concluding this analysis, we think we can state that the work to be done for an even more effective protection of health and the environment, despite the positive start, is considerable and can be summarised in the following points:

a) We appreciate how today’s society is developing a new sensitivity towards risk, the methods with which technical-scientific research perceives it, tackles it when it is not possible to quantify it, must (or can) answer to the eventual threats (real or potential) in urgent situations.

b) The awareness that the assessment of the risk comes with a variable level of scientific certainties must increase. Zero risk does not exist. Only a systematic study of the biological effects consequent to being exposed to certain agents, manipulations, treatments (including medical-surgical ones in continuous evolution, implicitly burdened by various types of risk often not clearly foreseeable), carried out with rigorous scientific methods, can significantly reduce the unforeseeable margin of risk.

c) In adjusting the most accurate methods of control, industries, universities, public and private research institutes must collaborate to define high standards and for the elaboration of criteria and guidelines for the interpretation of data. This collaboration, nourished by scientific dialogue and debate, is a necessary condition to face the preoccupations that arise with the development of anthropic activities on the environment and biotechnologies.

d) To this end, it is essential to have technically defined control criteria, which must be specific to the problem under consideration.

e) The researcher's duty is to determine the efficacy, reliability, efficiency and breadth of the interval of variability within which the feared effects, for the purpose of control and security, can manifest themselves.

f) Specific research programmes aimed at evaluating the controversial aspects to ascertain that the precautionary procedure adopted is straightforward.

g) Every public authority's decision regarding the issue under investigation should be preceded by an expert evaluation carried out also looking at conflicting arguments, which should not overlook taking into account minority opinions.

h) The definition of acceptable risk does not strictly concern the scientist but it depends on a joint judgement of experts in legal, ethico-moral, economic and political disciplines, formulated in an open and transparent dialogue with public opinion, particularly if directly interested in the surrounding environmental risk (for example dangerous industrial settlement).

i) National and European legislation concerning the assessment procedures for risks associated to interventions on living organisms and to the dissemination of products destined to consumption is increasingly broad and articulated. Object of particular attention are – today – genetically modified organisms and their derivatives, but the focus must be shifted to other significant sources of risk for human health.

j) In general, the assessment of the risks linked to new technologies (carried out by comparison) should not slow down and stop the introduction on the market of new products that can show how to overcome old risks.

k) The "precautionary principle", the ethico-legal value of which is reinforced by clear scientific justifications can be a very useful tool in this reflection fully aware of contemporary society, but it must be "properly" used – waiting for scientific clarity on the controversial topic – and not as simple current tool in social Governance. In addition, the "specific gravity" to give to this principle in positive law, not being foreseeable – at least in the continental system – to abandon the legislation founded on authorised standard parameters.

l) The correct application of the precautionary principle can stimulate scientific research also for the purpose of making industrial applications safer.

TABLE 1 SHORT GLOSSARY OF DEFINITIONS

Risk: it is defined as the sum of the probabilities and the seriousness of an adverse effect

Scientific-rational approach of risk assessment: (generally) distinguishes three procedural phases:

1. Risk identification;
2. Estimation of the level and scope or the risk's potential damage;
3. Assessment of the acceptability of the risk compared to other risks.

User/payer's principle. Stated by the OCDE in 1989 ascribes to the user the cost of an activity that is the source of pollution.

Polluter/payer principle. Stated by the OCDE (1972), mainly ascribes to the individual who pollutes the costs of the measures of prevention and fight against pollution.

Preventive principle. Principle according to which, in the presence of real risks, the dangerous induced effects of which are already established, even though the probability for the risky event to happen could be assessed in a different way, is carried out with adequate measures to avert/contain the risk.

Mitigation principle. Even if it can demonstrate that the risk of incident is low, it is supposed nevertheless that the accident can happen. Procedures are put in place to allow the decrease in the consequences of the incident for man and the environment.

Precautionary principle. Principle according to which the absence of certainties, taking into account the scientific and technical knowledge available at the time, must not delay the adoption of effective and proportionate measures aimed at preventing the risk of serious and irreversible damage in the environment for an economically acceptable cost.

Foreseen applications for the "precautionary principle"

In the protection of the environment and the safeguard of human, animal and plant health. The Communication of the Commission on the precautionary principle (N1,2000) says:

(Maastricht/Amsterdam)

"Although the precautionary principle is not explicitly mentioned in the Treaty except in the environmental field, its scope is far wider and covers those specific circumstances where scientific evidence is insufficient, inconclusive or uncertain and there are indications through preliminary objective scientific evaluation that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the chosen level of protection"

(Durable) sustainable development.

Introduced in the Rio Conference (1992) is considered as the fundamental principle (Art. 1) of every policy of environmental treatment and protection. It says:

“durable development tends to satisfy fairly the needs relative to the development and environment of present and future generations” (art. 3).

A more concrete formulation states:

“development is durable (sustainable) if future generations will inherit a quality environment at least equal to the one received by previous generations”.