The principle of precaution and the nano-techno-sciences

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Abstract

The rapid development of the nano-techno-sciences and the belief that they represent threats to the survival of the planet have led groups of organized civil society to request moratoria on nano-techno-scientific research, based on the principle of precaution. This article takes off from the finding that this principle provokes debates around its concept, its form of application and its bioethical implications. Here terms such as "risk", "danger", "uncertainty", "ignorance", "prevention" and "precaution" are confounded as synonyms which can lead to policy decisions that are at times "exaggerated". Applied almost always as a measure of stewardship of the environment, the principle of precaution has become an important regulatory principle of the techno-sciences, because it is believed that together with the potential benefits, they bring threats to life on the planet. The techno-sciences are not autonomous, but rather entities conceived, created and managed by human beings. Thus there is no way to attribute an inherent risk to any and all techno-scientific products.
Keywords: Bioethics. Precaution. Nanotechnology. Risk management.

Resumo

Princípio de precaução e nanotecnociências

O rápido desenvolvimento das nanotecnociências e a crença de que representam ameaças à sobrevivência no planeta têm levado grupos da sociedade civil organizada a pedir moratória para as pesquisas nanotecnocientíficas, baseando-se no princípio de precaução. Constata-se que esse princípio suscita debates em torno do conceito, da sua forma de aplicação e de suas implicações bioéticas. Alguns termos como "risco", "perigo", "dano", "incerteza", "ignorância", "prevenção" e "precaução" são tomados como sinônimos, o que pode levar a decisões políticas por vezes "exageradas". Aplicado quase sempre como medida de tutela do meio ambiente, o princípio de precaução tem se tornado importante instrumento regulatório das tecnociências, por se acreditar que, junto com os potenciais benefícios, trazem ameaças à vida e ao planeta. As tecnociências não são entes autônomos, mas, sim, pensados, criados e manejados pelo ser humano. Portanto, não há que atribuir um risco inerente a todo e qualquer produto tecnocientífico.
Palavras-chave: Bioética. Precaução. Nanotecnologia. Gestão de riscos.

Resumen

Principio de precaución y nanotecnociencias

El rápido desarrollo de las nanotecnociencias y la creencia de que representan amenazas a la supervivencia en el planeta, ha llevado a grupos de la sociedad civil organizada a pedir una moratoria para las investigaciones nanotecnocientíficas, en base al principio de precaución. El artículo parte de la constatación de que este principio suscita debates en torno del concepto, su forma de aplicación y sus implicaciones bioéticas. Algunos términos como "riesgo", "peligro", "daño", "incertidumbre", "ignorancia", "prevención" y "precaución" son confundidos como sinónimos, lo que puede conducir a decisiones políticas, a veces, "exageradas". Aplicado casi siempre como medida de tutela del medio ambiente, el principio de precaución se ha tornado un importante instrumento regulatorio de las tecnociencias por creerse que, junto con los potenciales beneficios, traen amenazas a la vida y al planeta. Las tecnociencias no son entes autónomos, sino que son pensadas, creadas y manejadas por el ser humano. Por lo tanto, no hay que atribuir un riesgo inherente a todo y cualquier producto tecnocientífico.
Palabras-clave: Bioética. Precaución. Nanotecnología. Gestión de riesgos.

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Declaram não haver conflito de interesse.

Principles are indisputable statements (...) that do not have the flexibility to give way when faced with other principles, or impose themselves according to their contextual needs, being, therefore, *of general validity and enriching of an evaluative defense*, such as, for example, the conservation and preservation of the environment. As such, *principles really are action guides that summarize and encapsulate a whole moral theory and thus, in a shorthand manner, assist a moral agent in making a moral decision* [2].

The precautionary principle is understood as "a relatively new concept, directed by action" when faced with "the risk of serious and irreversible harm", represented, for example, by global environmental damage. According to this principle, we should not "forgo taking action" against the "pretext of scientific uncertainty". The conception of rationality that lies beyond the mere preoccupation with "technical effectiveness" and "scientific certainty", is, however, often considered to be an "anti-progress principle" [3].

Considering the level of debate surrounding the concept, its form of application and its bioethical implications, it can be argued that the precautionary principle is the subject of semantic, political and moral controversy, as it is both misunderstood and poorly accepted. Indeed, considering the lack of conceptual clarity and concreteness when applying this principle, interest groups have tried to impose their ideological conceptions to encourage or oppose its application [4]. On one hand, for example, are the alarmists and/or techno-science-phobes, who, in the name of environmental protection and the conservation of species, try to convince society that certain human activities, among them deforestation and techno-scientific development, are inherently threatening and as a result, should be at least curbed. Their argument is based on the precautionary principle, whose behavioral maxim is to use the avoidance of harm, even if uncertain, as a justification for paralyzing such activities. On the other hand, "progressives" and/or techno-science-philes, in the name of economic and social development, interpret the principle as only a directive without coercive power, which, when curbing certain human activities, could prevent the growth of humanity.

Conceptual heterogeneity maintains the discussion concerning this principle in vogue and offers opportunities for new definitions or interpretations. Contrastingly, however, it also impedes the use of the principle as an effective political tool [5]. As such, positive law, for example, values the precision of actions performed and the causal link between these actions and their results (or consequences) when offering decisions. Such requirements (precision of actions and causal link) are not always present when appealing to the precautionary principle in the context of deterring a potentially threatening activity. Perhaps because of this, the Treaty on European Union makes only one reference to the precautionary principle, and does not define the concept. Indeed, *despite the growing jurisprudence including important decisions of the [European] Court of Justice, the legal community remains divided over the meaning and applicability of the principle* [6].

Another discussion point refers to how the principle is applied – through banning, paralyzation, revision or substitution of the activity in question – and its bioethical implications. On the one hand, its defenders invoke the precautionary principle when they consider that the activities in question threaten, in a serious or irreversible manner, the environment or human health, even when scientific uncertainty exists between cause and the effect [7,8]. This position is coherent with the bioethical principles of human dignity and human rights, from a benefit-harm perspective, as well as in terms of protecting the environment, the biosphere and biodiversity [9].

Contrastingly, critics of the principle argue that its application, based as it is on the uncertainty present in the link between an action (scientific research, for example) and its results (the products of such research, for example), may delay scientific and technological development [10]. Indeed, among the end products of science and technology are improvements in human health, social development and the environment – issues forming part of the *Universal Declaration on Bioethics and Human Rights* (UDBHR), articles 2º, 14, 15 and 17 [9].

Despite these polarized positions, the benefits being protected and preserved are the same: human health and the environment. In other words, the removal of risks depends both on the precautionary principle and scientific and technological development. But due to its vagueness and lack of precision, and because it does not suggest what type of action is to be taken or not taken, the precautionary principle cannot serve as a guide for decision making [11].

In particular, the precautionary principle can sometimes be seen as the topos of a rhetorical discourse from northern countries aimed at their southern equivalents, seemingly in favor of the environment and human health, but which effectively creates, in the latter, policies that are contradictory

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to the principle, such as the liberation of pollutants through industrial activity.

In fact, the objective function of the precautionary principle is to impede or curb the real and potential negative impacts on the survival of life on Earth, whether through individual, collective or institutional action. In this context, the intimate relationship between the principle and bioethics, notably represented by the UDBHR, can be seen. As the precautionary principle deals with uncertainties related to the consequences of human actions, the decision to apply it or not should be fully considered, as should what form such application should take. Furthermore, due to its relationship with the nature of the risk involved (reversible, irreversible, serious individual, collective, with the magnitude and extent of possible damage (local or worldwide or prolonged or not in time) and, even, with the type of information used (scientific, economic or political data, or perceptions of risk to society).

Definition of precautionary principle

Some terms related to the principle are examined below, as their use can cause confusion, "risk", "danger", "harm", "uncertainty", "ignorance", "prevention" and "precaution".

Common sense defines "risk" as relating to possible negative events and the likelihood of such events transpiring. In ideal hypothetical situations, a risk is something quantifiable, with known probabilities and a negative value [12]. As a technical term, meanwhile, "risk" can assume a qualitative meaning, when designating the occurrence or non-occurrence of undesirable consequences, or a quantitative meaning, when representing the probability of an undesired event occurring or the statistical significance of the severity of such an event [13].

The quantitative meaning considers risk as an autonomous entity that invades the daily life of society with cost-benefit calculations, which may influence the configuration of identities and the forming of subjectivities, as well as increasing awareness of health threats, with the consequent, almost frantic demand, for risk control measures, even if they are not rationally justified and there are no guarantees regarding the preventive or protective results of such measures [14]. For Aven [15], *risk is primarily a judgement, and not a fact* (...) *and expresses uncertainty about the world* [16].

In contrast to "risk", the term "danger" expresses a real and current threat to well-being, and can develop into harm, if preventative measures are not taken.

"Harm" can be described as the current or future state of confirmed damage, such as a) physical, when the material (understood as the body or substance that occupies a place in space) suffers a negative effect; or b) moral, when the value system of individuals and/or collectives is not respected.

"Uncertainty" denotes unknown or imprecise probabilities, related to unwanted events. It is a quantitative component that is attributed to risks. As one cannot "risk" at a time of uncertainty and, in certain situations, the observer involved is urged to act, some theories apply probabilities to uncertainty. In other words, assigning probabilities to uncertainties is essential in decision making, whether in public health policies or in other areas of life. This is the "Bayesian inference" in which probability is a measure containing some prior information and knowledge of the events, calculated and inserted by the observer [15]. The association between uncertainty and degree of knowledge is known as the "epistemic uncertainty", resulting from the lack of knowledge of the observer regarding the probabilities of the event [17].

"Ignorance" may be synonymous with uncertainty (or lack of knowledge), in a situation where the probabilities cannot be estimated because of a poor analytical base, or in a situation where the determination of the results (consequences) is problematic [18]. In this way the state of ignorance is marked by the difficulty in establishing a model to determine the consequences of an activity; the model may even exist, but is not accepted by the scientific community[19]. As such, ignorance is a non-defined relationship between the consequences and causes – however, it is therefore an uncertainty that is scientific in nature, and that is relevant in context of the precautionary principle.

Decision makers often apply the terms "prevention" and "precaution" indiscriminately, as if these two associated protective measures had the same motivations, without distinguishing between potential and real harm. However, it is possible to distinguish between the two based on the concepts of certainty and uncertainty and of the risk, danger and harm related to an event. Therefore, the observer will have the capability, however questionable, of making a decision by applying one or other of the measures.

Prevention is applied to activities in which the harm is credible (scientific certainty), imminent

or in progress, while precaution is invoked when there is uncertainty that the harm has occurred or there is partial knowledge of cause and effect. The preventive measure may occur before or after the activity considered dangerous, by preventing, reducing or eliminating harm. With precaution, the action always comes before the fact. What decides the action to be taken - prevention or precaution - is total, partial or even misleading understanding of the possible cause.

In short, there is no universal definition for the precautionary principle, as literature offers several suggestions, which appear to be vague and contradictory, as well as possessing different versions [20-23]. Some versions, in defining the application of the principle, resort to the uncertainty of the risks involved or the causal link between action and harm or the burden of proof in terms of the safety of the activity [22,23].

Another important point highlighted by Harris and Holm [24], is whether, in the context of human health, it is sufficient and/or necessary for harm be serious and whether the number of people affected is relevant, which leads to a questioning of the parameters that indicate the degree of seriousness of the harm. If the harm is serious, the question must be asked as to which ethical doctrine would be best applied here: utilitarianism? The answer is apparently yes, since the formulations of the principle emphasize the motivations of actions, or the qualities or character of the agents. According to these authors, extreme weighting is given to the harm that activities cause, eliminating the comparison with potential benefits, which leads the precautionary principle to no longer be considered a valid moral principle.

Origin of the precautionary principle

The concept of precaution has distant origins, with many authors deriving the theory behind it from the Aristotelian idea of "prudence" or "moral judgment" (phronesis), although modern experimental science cannot be based on the logotheoretic Aristotelian conception [3]. In particular, precautionary measures have always been used in medicine and public health in order to avoid exposing populations and individuals to risk. One of the first such precautionary actions occurred in London in an attempt to curb the cholera epidemic in the city [25].

Precaution was raised to a principle of positive law with the application of *Vorsorgeprinzip* (which means the precautionary principle in German) in the Clean Air Act of 1974, in Germany 4. In the 1980s, the principle was widespread throughout northern Europe and subsequently became part of the global political agenda on environmental protection, finding its highest expression in the Declaration of the United Nations Conference on Environment and Development in 1992 [7].

In public health, whose main objective can be seen as the identification and reduction of risk [26], the precautionary principle is allied to epidemiological approaches, adding the measurement of the uncertainty of harm and the subsequent interruption or stoppage of causes with possibilities or potential to cause damage to such approaches [4]. Therefore, *the precautionary principle tends, due to the pressure of public opinion and the fact that public officials may be subject to legal action, to assume a meaning closer to a negative obligation than what had been explicitly formulated in legal texts dedicated to the environment* [27].

The concept of risk would have introduced a speculative element into epidemiology, expanding the field of study of the associations between events relevant to health such as chronic non-communicable diseases and their prevention, leaving the studies of infectious diseases to microbiology research, made possible by the advent of laboratory techniques [28]. According to Ayres, for MacMahon, chief spokesman of epidemiology of risk, epidemiology You can not claim to say, but suggest, the causal links that hard biomedical sciences should definitely establish. [29].

Risk must be based on: a) the identifying of possibility and probability, or in other words, the quantification of risk; b) the unification of the elements of the health-disease processes, or in other words, the characteristics of these events reduced to a single measure (the concept of risk and its properties), and c) the expectation of the stability of the cause-effect processes, which allows the creation of risk prevention models [30] that depend on the types of determinant of the events to suffer intervention. Even if fallacious, such models are an attempt to respond to society, indicating that events and risks are known and possibly or probably preventable. Risk prevention can be temporal (when applied to objects observed in the present or projected in the future, based on observations of the past) or spatial (when extrapolated to unobserved objects, based on observations of observed objects) [30].

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Justification for applying the precautionary principle

Two main elements accompany virtually all definitions of the precautionary principle: threat and uncertainty. It can be stated in this case that the threat refers only to the possibility of physical, irreversible or reversible harm to humans or the environment, whether serious or not. These threats require no scientific corroboration, and action can be taken without having to remove scientific uncertainty, taking into account only the severity and irreversibility of the potential harm [3].

However, as a *potential for good or ill* [31], the application of the principle can deny either society or the environment of the potential benefits of a certain activity while protecting them from the potential damage from the same activity, although the precautionary principle gives more weight to harm than benefits. Therefore, it is possible to argue that the precautionary principle *cannot be a valid rule for rational decisions* [32], as its application is based on the uncertainty of risk and the decision and the subjectivity of the observer, with rationality assuming a background role. Moreover, precaution is contextually constructed, which further complicates its application in response to an uncertain risk [33].

Indeed, it is a mistake to believe that scientific truth can prove the existence or absence of harm of any activity, as *demanding certainty about the absence of harm before authorizing an activity (...) is no more rational than requiring certainty about the existence of harm (...) to take preventive measures* [34].

One should also highlight the role of the social perception of risk in decision-making, as the perception of risk *refers to the beliefs and feelings of people about the nature of threatening events, their qualitative features, its benefits and its acceptance*[35], which are influenced by the information available. In this case, the psychosocial impact is crucial to define the degree of risk that society perceives about a certain activity [36]. Human activities that are comparatively safer than others are perceived as having a greater degree of risk, because of the number of people affected at the same time by a single adverse event - air travel, for example.

The perception of risk also depends on the scope of assistance and/or protection that an activity receives from the state. For societies with guaranteed quality public health services and systems, the definition of limits of risk to health is safer, as such factors reinforce resilience [37]. On the other hand, in societies whose health services are nonexistent, precarious or inaccessible due to high cost, risk perception acquires a status of real and unavoidable threat: (...) *there are situations where precarious socioeconomic conditions are inevitably linked to major difficulties in reducing risk, inexorably increasing the social vulnerability of certain groups at the expense of others* [38].

For example, the fear created by the possibly irreversible risks posed by global warming has transferred the sense of such irreversibility of harm to other human activities, such as new techno-sciences, suggesting a global shifting in perception of risk. With this, measures of prevention and precaution have also changed, and should take into account not only the scientific data available and calculations of probability, but also social perceptions of risk. One example is the influence of risk information on the moralization of people and about *the construction of a predominant morality* [39].

It is necessary to consider that risks, when overestimated, can cause an unnecessary increase in spending on measures of protection and thereby a reduction in spending in areas such as health promotion and education. In addition, this exacerbation of risks can create a certain "insanity" in modern society, resulting in a lack of stability and security [14]. Therefore, finding a formula to justify the application of the precautionary principle is no easy task as it is necessary to consider multiple factors, including the type of threat, the target of the threat, the scientific information about the risks, the balance between benefit and harm, the extent of the harm, the reversibility or irreversibility of the harm, the socio-cultural context, the social perception of the risk, and the political climate.

Applications of the precautionary principle

The precautionary principle is often invoked as an environmental protection measure, a complex system of interrelations concerned with the possibility, however remote or uncertain, of some disorder in the interconnecting pathways, and whose feedback loops can enhance these possibilities [17]. Recently, however, the principle has become an important regulatory instrument of scientific and

technological activity, as well as the development of their products [40]. In Brazil, a case in point occurred in the 1990s with the prohibition, by the Federal Court, of genetically modified soybean cultivation (round-up Ready, RR) until the issue was regulated and an environmental impact study and environmental impact report were carried out (EIA/Rima) [41].

In the 1970s, advances in research into DNA manipulation raised questions about the risks associated with the forced introduction of genetic material from one organism into another. The potential risks are such that scientists have publicly stated their concern about such developments and called for a moratorium on these surveys [42]. In February 1975, during the International Asilomar Conference on Recombinant DNA Molecules, California, USA, scientists discussed scientific advances and outlined guidelines for conducting research with DNA [43].

Human cloning is another morally controversial issue, with relevance to the precautionary principle. Indeed, the *Universal Declaration on the Human Genome and Human Rights* refers, implicitly, to the precautionary principle in a global context, when banning reproductive human cloning, arguing that such an activity was prejudicial to human dignity [44], and imposing the universal duty of respect for human dignity, as cloning, by interfering in the *intrinsic finalism of natural processes*, [would prove morally] *bad in itself* [45]. In other words, the arguments against human cloning do not take into account a *therapeutic or preventive medium to be used in cases of actual need or legitimate wishes* [46]. For Schramm [45], in respecting the procreative autonomy of women, reproductive cloning would not be morally different from assisted fertilization, according to a utilitarian vision.

On the other hand, the cloning of human organs and tissue, because of its therapeutic and preventive purposes, would be more easily accepted by society, *provided appropriate biosecurity measures and the principle of equity were respected* [47], as well as the *dialectic of prima facie principles of beneficence and non-maleficence (which have been the foundation of 'correct' health intervention since Hippocrates), respect for autonomy and free, informed consent, justice, and others which may come to be needed in order to live well* [48], as *the applications of research* (...)*concerning the human genome* (...) *shall seek to offer relief from suffering and improve the health of individuals and humankind as a whole,* as stated in paragraph "b" of Article 12 of the *Universal Declaration on the Human Genome and Human Rights* [44].

Among the existing definitions of the precautionary principle, it is important to include the World Commission on Ethics of Science and Technology of UNESCO (Comest): *When activities may lead to morally unacceptable harm that is scientifically plausible, but uncertain, actions shall be taken to avoid or diminish that harm* [49]. Morality, in the definition of Comest, comprises serious and irreversible harm to humans or the environment, unjust for present and future generations, without respect for human rights, both those that the bioethics of protection [50] considers violated - people who, *for some reason independent of their will,* [are unable] *of defending themselves, because of the unfavorable conditions in which they live or due to their abandonment by the relevant institutions that do not offer them the necessary support to face the condition they are affected by and trying to escape from* [51] – and the vulnerable, who, according to the bioethics of intervention [52], are all who are faced with *something that takes power away from* [them] *(another person, an institution, the State etc.)* [53].

The harm may only be a plausible hypothesis; that is, even if there is no probabilistic evidence of it occurring it should be treated as a serious possibility. The activity, in turn, must be subjected to a democratic selection process and an assessment of its moral implications, as well as its positive and negative consequences: *the choice of activity should be the result of a participatory process* [49].

Rapid scientific and technological development, and the speed of the spread of its impact, thanks to globalization, the elimination of boundaries between nations, and the deepening of scientific knowledge about the extent of these consequences, have challenged governments to respond effectively to the risks. A classic example is the development and consumption of genetically modified organisms (GMOs) in food, which are banned in some countries and allowed in others. At first, the paralyzation caused by the precautionary principle affected research into genetically modified plants, because of uncertainty about the harm they cause before a single plant had been developed [10]. In this understanding, as a variant of the *principle of risk aversion* [54], the possibility of a large scale disaster or catastrophe arising from a technological development would be enough to ban such development, even if it offered the chance of considerable benefit to humans [36].

In general, orders for moratoriums, prohibition, or postponement - which are actually precautionary measures - can be based on a fear of technology, paralyzing for a time or even cancel-

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ling research into science and technology. In other words, techno-science-phobia, when associated with naturalistic conservatism, removes the responsibility for the misuse of techno-sciences from political, economic and financial systems [55]. Therefore, the creative competence and the creator of the biotechnology and the increase of risks appear to have become inseparable because, *in choosing one, we inevitably also choose the other* [56].

In short, the literal interpretation of the precautionary principle could force the withdrawal of a drug from sale of because of its side effects; paralyze the exploration and production of oil due to the release of unhealthy gases; and banish nuclear energy as a leak could contaminate an area of hundreds of kilometers and perhaps thousands of living beings. However, if this principle is not to be taken literally, then surely one should call it a "guideline" or a "guide" but not a "principle" [57].

The precautionary principle in nano-techno-sciences

It was in the eighteenth century that science, technology and production started to become related and interact [58], a characteristic that is reproduced in the twenty-first century by nano-techno-science, which has resulted in large-scale investment and financial planning. Such massive applications probably accelerated the development and commercialization of products of nanotechnology, even before the assessment of their risks, which urged international and civil society organizations to invoke the precautionary principle to halt research into this field, and the consequent transfer of the results of such research to the market. Thus, moratorium orders respond to the trend of current policies to accelerate the commercialization of "nano-products" without careful assessment of the uncertainties that surround them [59].

In this sense, the report of the Royal Society and the Royal Academy of Engineering, UK - RS Policy Document 19/04 – is worth noting. This recommended precautionary measures for nanoparticles and nanotubes, considering the hazardous materials: (...) *the release of manufactured nanoparticles and nanotubes into the environment must be avoided as far as possible* [60].

In 2004, the European Commission included in its European Strategy for Nanotechnology activities in the ethical, legal and social fields (European activities in the field of ethical, lawful and social aspects - Elsa) and recommended the creation of a Code of Conduct for Responsible Research in Nanosciences and Nanotechnologies as a model of regulation and governance of nanotechnologies. The code, approved by the European Commission in 2008, outlines seven general points that should be considered in nanotechnology research: adequate information to the public; sustainable development; the precautionary principle; the integration of the whole society; investigative excellence; innovation, and responsibility [61].

The Intergovernmental Forum on Chemical Safety, of which Brazil is a member, approved, in September 2008, eight principles that should govern the monitoring of nanotechnologies and nanomaterials, of which the precautionary principle is the first and most important [62]: 1) the precautionary principle: the submission of nanotechnologies to this principle, and the possibility of impact on health and the environment; 2) mandatory regulation of nanotechnology: the introduction of specific regulations for nanotechnology; 3) health and safety of the public and workers: introduction of mechanisms to prevent exposure to genuinely or potentially harmful nanomaterials; 4) environmental sustainability: the life cycle analysis of nanomaterials in the environment, in health and in occupational safety, before releasing them on the market; 5) transparency: mandatory labeling for nanomanufactured products or those containing nanomaterials; 6) participation of citizens: involvement of society in the discussion and decision-making process related to the development of nanotechnology; 7) consideration of social and ethical impacts: allocation of public investment to nanotechnologies, taking into account the social impact, ethical assessment, equity, justice and local interests, and 8) the responsibility of the producer: accountability of all involved in the chain of nanotechnology-based products for the damage that exposure to nanotechnology may cause.

Since 2003 the Action Group on Erosion, Technology and Concentration has proposed a moratorium, especially for products that contain nanoparticles [63]. In 2010 the European Parliament recommended in a moratorium on the production of food that used nanotechnology in its processing, packaging and nanoingredients, until a risk assessment study had attested to their safety [64].

It is important to note that the application of the precautionary principle should seek a clear distinction between credible threats and unlikely threats; that every decision should be based, as far as possible, on scientific evidence; that a greater threat

should take priority over a minor threat; that in the case of a previous negative event, such as a death demonstrably caused by certain types of cancer, and due to a lack of therapy with nanoparticles (if the only treatment) – the use of nanoparticles should be avoided, even though they can subsequently cause adverse effects; that, in situations where the human factor has an essential role in the end-use of scientific development, regulation or guidelines should be applied before any paralysation or ban is applied [65].

The application of nanotechnoscience to the precautionary principle requires a range of analyses, as it is not sensible to attribute the connotation of inherent threat to all branches of this technology because, while the reports and scientific papers on nanotechnoscience refer to definitions, terminology, toxicity, safety and regulation - doubts and uncertainties still remain, partly due to the false notion that all nanoparticles, without distinction, have an unknown and specific mode of toxicity [66].

Indeed, due to the discovery of increasing number of nanoparticles, the lack of knowledge about their toxicological behavior and the lack of validation of toxicology tests to evaluate the safety and risks, data remains insufficient [67-70] to guarantee the release, marketing and use of nanotechnology products. However, the wide range of scientific literature on the toxicity of nanoparticles, in indicating the certain or uncertain risks of these materials [69], and with the status of a primary source of information available [71], could serve as guidance for decision-making, the creation of legal provisions and even to the appropriateness of conducting research on the part of (nano) scientists.

A good example is the report by the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) – a European Union agency responsible for protecting the health of consumers - on the safety and risks of nanomaterials. According to the report, *the Committee reviewed the data and scientific knowledge currently available* [to propose] *a number of observations* (...), *recommendations* (...) *and suggestions for the improvement of methodologies* [for the assessment of risk of nanoparticles for human health and the environment] [72].

Another notable example is the report of the National Institute for Occupational Safety and Health (NIOSH) – a US agency responsible for protecting the health of workers – on strategies to control worker exposure during the handling and production of nanomaterials. Among other things, the document warns: with *the rapid growth* [of the commercial applications of nanomaterials], *it is essential that producers and users of nanomaterials ensure a safe and healthy work environment for employees who may be exposed to such materials*. *There are currently no regulatory standards for nanomaterials in the United States. However, NIOSH issued* [documents] *on* [limits] *of exposure* to nanoparticles of titanium dioxide and carbon nanotubes [73].

Considering these points could lead to a rationalization of financial costs and research time. Indeed, where financial resources are scarce, such a rationalization becomes essential for the allocation of human and financial capital to solving real local problems, thus reducing environmental costs and minimizing health risks.

Another point to emphasize is the difference between the terms “risk” and “consequences”, commonly treated as synonyms: risks may or may not ultimately occur; while consequences are accurate, expected results. It is common to observe, in both the popular and the specialist media, the reference to the “consequences of nanotechnoscience” synonymously used in correspondence with the “risks of nanotechnoscience”. Such a terminological slip gives the idea that the nanotechnoscience is truly a source of damage, leading to the public perception that it is a dangerous technology and encouraging movements supporting its banning or paralysis.

Final considerations

The debate surrounding the precautionary principle is complex and divided, in seemingly equal proportions, between for and against arguments. Moreover, decision making on the subject – as we have tried to show – is politically and ideologically influenced. Indeed, the non-uniformity of the definition of the precautionary principle can have significant global repercussions.

On the one hand, the environment, health and social development may become vulnerable when exposed to different types of risk, due to the permission or prohibition of certain activities by countries. Asbestos, for example, was banished from most northern hemisphere countries because of its proven carcinogenic effects, something that has not occurred in many southern hemisphere countries, such as Brazil, where production, importation and use of the material continue [74], despite the warnings of health workers since start of the last century [75,76]. On the other hand, international trade may be affected by bans or permissions on the entry of products classified as threatening or not to health or the environment. An

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example is the authorization of the growing of some genetically modified plants in the EU, such as corn, cotton, sugar beet, sunflower and soya [77], and the prohibition of others. Thus, the European Union's position makes the trade of some cultivars impossible.

A recurring criticism of the application of the precautionary principle is that it does not provide a solution or concrete guide [36,51], but merely creates a forum for discussions on the undesirable, often unreal consequences, of human activities, and is therefore of little use to decision-making within public policies [78]. In this case however, a review of the formulations of the precautionary principle formulations should consider the potential benefits and avoid "prophetically" overestimating damage, in order to allow the probabilistic calculation of near real risk and the cost-benefit ratio.

Considering these factors, the precautionary principle can be applied if the activity proves unfavorable to the sustainable quality of life, including here the three areas relevant to bioethics - health, the environment and social aspects – as it can be conceived as the *systematic study of the moral dimensions (...) of the life sciences and health care* [79], or in other words, as a toolbox to deal with the *impact, positive or negative, of biotechnology on the life and/or quality of life of human beings and possibly the quality of life of non-human animals and the quality of natural environments* [80], and as a field of investigation capable of answering *deep philosophical questions about the nature of ethics, the value of life, what it is to be a person, the significance of being human [and about] issues of public policy and the direction and control of science* [81]; as well as being a place of *intersection of a large number of disciplines, [a] meeting place, more or less confrontational, of ideologies, morals, religions, philosophies, [and] challenges for a great many interest groups and constituent powers of civil society: patient organizations, medical staff, animal protection and environmental groups, agribusiness, pharmaceutical and medical technology industries, and bio-based industries in general* [82].

It is also important to consider alternative technologies, which meet, as a minimum, at least the same requirements as those existing or planned, potentially or supposedly threatening, but without their limitations or problems [40]. The government may, in this case, encourage their development, without ignoring, in the context of a lack of resources combined with a utilitarian perspective, real and social necessities.

The precautionary principle often depends on the development of an activity or ability that provokes it. In practice, the paralysation will almost always occur when the event is already underway and the consequences have already begun to manifest themselves. In this sense, Almeida-Filho and Coutinho [30] propose the introduction of a contingency mode to the concept of risk, which is characterized by the unpredictability of current and future events.

As a result of the alarmist perception, above all from (nano) techno-science-phobics and disaster analysts, nanotechnoscience was born stigmatized. Such a perception does not take into account the fact that *to live today, involves accepting (voluntarily or not) modes and/or standards of exposure to certain risks* [83] and that development – be it biomedical, technological, social, economic or political - depends on this assumption and the subsequent attempt, due to unpredictability, to prevent and/or protect oneself against risks. Therefore, *it is for Bioethics to exercise an ethical approach to scientific knowledge that not only presents unpredictable developments (like any other), but is also based on such unpredictability* [84].

In conclusion, the frequent attribution of inherent risk to new technology can be characterized both as a "prophecy" and as a fundamental error in the analysis of these technologies, either because there has not yet been time for the harm (if any) of such practices to be demonstrated, or because they are not autonomous entities, but are created and managed by humans in their techno-scientific and bio-scientific practices.

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