

A Review of Brazilian Courts understanding of the “Precautionary Principle” in Biotechnology Law

Análise do entendimento dos tribunais brasileiros sobre o “Princípio da precaução” no biodireito

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Risk is not the same as catastrophe, but the anticipation of the future catastrophe in the presence. As a result, risk leads a dubious, insidious, would-be, fictitious, allusive existence: it is existent *and* non-existent, present *and* absent, doubtful *and* real. In the end it can be assumed to be ubiquitous and thus grounds a politics of fear and a politics of prevention. Anticipation necessitates precaution and this obeys, for example, the calculation: spend a cent today, save a Euro tomorrow – assuming that the threat which does not (yet) exist really exists.

Ulrich Beck (2009, p. 3)

Abstract

The aim of this essay is to analyse how Brazilian Courts are interpreting the Precautionary Principle concerning biotechnology or the so-called bio-engineered food and new drugs, or, in a generic term, Genetically Modified Organisms. This issue is very much relevant in present times since several questions arise from such interpretation. This essay is divided into three parts. The first one analysis the Precautionary Principle itself, its concept and criticisms from scientists of its

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indiscriminate use as well as its relation with risk assessment in biotechnology. The second part brings a brief review of the evolution of Brazilian Law concerning biotechnology, genetic modified organisms and the bureaucracy involved in their approval in the country. The third part consists in a review of important court decisions in Brazil that set off standards for other judgments. Based on these elements, the conclusions from the initial questions shall be presented.

Keywords: Biosafety. Genetically Modified Organisms. Precautionary Principle. Brazilian legal system. Brazilian Court Decisions.

Introduction

It is widely recognized by agricultural economists, biologists and other scientists that the world has to increase food production in the next decades in order to feed the growing population of the earth. The means by which this shall be done, considering a limited amount of resources, are under discussion at the present time. Will natural or organic agriculture be able to nourish everyone properly in a near future?

The discussion of this matter has taken time and effort both from scientists and governments, especially when it comes to how the genetically modified organisms (GMOs) should be regulated. Several international treaties and internal regulations have been issued, and most of them bring, at some extent, the so-called Precautionary Principle.

This principle is supposed to guide the decisions on whether or not GMOs should be cultivated or approved for human or animal consumption. Nevertheless, its formulation and content are neither uniform nor clear.

Basically, it states that if there is not absolute certainty about the safety of a certain GMO for human health or environment, such GMO should not be cultivated or consumed, even if no actual harm may be evidenced.

The aim of this essay is to analyse how Brazilian Courts are interpreting the Precautionary Principle concerning biotechnology or

the so-called bio-engineered food and new drugs, or, in a generic term, Genetically Modified Organisms - GMOs. This issue is very much relevant in present times since several questions arise from such interpretation.

Some of the most important are: are we willing to take risks for science developments? To which extent? Does the use of the Precautionary Principle substitutes risk analysis? Can it impair science development? Is it compatible with scientific methods, a political tool or a decision-making criterion?

In this sense, by analysing some key Court decisions in Brazil, we intent to find out whether or not Brazilian Judges are considering theses matters when judging about biotechnology issues.

This essay is divided into three parts. The first one analysis the Precautionary Principle itself, its concept and criticisms from scientists of its indiscriminate use as well as its relation with risk assessment in biotechnology.

The second part brings a brief review of the evolution of Brazilian Law concerning biotechnology, genetic modified organisms and the bureaucracy involved in their approval in the country.

The third part consists in a review of important court decisions in Brasil that set off standards for other judgments. Based on these elements, the conclusions fro the initial questions shall be presented.

1 The Precautionary Principle

There are many variations of the so-called Precautionary Principle, which is based in the belief that "better safe than sorry". According to Burnett (2010, on line),

[...] the most widely cited is the Wingspread Declaration, which states 'When activity raises threats of harm to human health or to the environment, precautionary measures

should be taken even if some cause and effect relationships are not fully established scientifically.¹

The Cartagena Protocol, entered into force in 2003, was the first legally binding international document that, in regulating biotechnology, includes the precautionary principle, as basis to domestic regulations on GMOs and also allows countries to refuse shipments of GMOs considered to be unsafe, even without solid scientific evidence (AHTEENSUU, 2010, p. 59).

In broad terms, the precautionary principle, applied specifically to biotechnology, requires that any new technology involving GMOs must be previously proved not to cause any harm to human health or to environment.

As per Burnett (On line), these are very difficult criteria to meet, and, nevertheless, have been applied broadly in European Union, where, until 2010, only one genetically modified crop had been approved, as opposed to other countries where a variety of GMOs were cultivated as off the early nineties. In fact, it is nearly impossible to prove a negative, and it is what is being required when it comes to GMOs. Belt (On-line, p. 185) affirms "Shifting the burden of proof to the proponents of biotechnology makes sense only if required standard of proof is also specified"². Until now, none has been defined.

Agricultural economist Dennis Avery states that if farmers decided to use completely "organic" practices, the amount of cultivated land would have to double in the until 2050. That would be harmful especially

¹ The Wingspread Academic Conference on the Precautionary Principle took place in January 1998, in Wisconsin, EUA. Before that, the Precautionary principle (although not expressly mentioning the word "principle") has been posed in the Rio Declaration of the United Nations Conference on Environment and Development in 1992, in the following terms: "In order to protect the environment, the precautionary approach shall be widely applied by Stated according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation". After that, the principle has been present in several international conventions, conferences and treaties.

² The author adds "The new European Directive surely places a heavy burden of proof on biotech companies intending to introduce GMOs. Whether or not they are able to take that burden on their shoulders will partially depend on the definition of standard protocol or methodology for conducting environmental risk assessment"(idem, p. 195)

to native wildlife because using more to agriculture necessarily means to convert forests and other biodiversity into fields for producing food (1999, p.1-3).

On the other hand, since 1995, when the first genetically modified crops were approved, the adoption of biotechnology in agriculture has only increased, especially in countries like United States, Canada, Argentina and Brazil.

The point to be clarified is whether the precautionary principle would be able to keep people and environment free from harm arisen form GMOs and if, by doing so, it would prevent necessary food technology from developing. In addition, would risk assessment be left aside by the indiscriminate use of such a principle?

The first difficulty in using the precautionary principle comes from the fact that, although it has been evoked for the last decades to guide public policies, especially regarding health and environmental issues, there is not a uniform formulation on its content. (BURNETT, 2010, online).

Although the most widely used is the one presented in Wingspread Conference, there other formulations, some stricter, such as those which propose that no technology shall be used until it can be proved to cause no harm to humans or nature, and other milder formulations.

Ahteensuu (2014, p. 59-60) informs that the Precautionary Principle formulation has been divided into two general categories: (i) the strong (or strict) form, according to which one should not use new technology unless its harmless in certain – adopted by the Wingspread Conference; and the (ii) weak (or active) formulation according to which lack of full scientific certainty is not sufficient justification for preventing an action that might be harmful.³

³ Belt (on line, p. 185) states that "strong version adopted by many environmentalist organizations is logically untenable, while the weaker versions espoused by the European Commissions and enshrined in international treaties are rather vague and ill-defined. The contested role of the Precautionary Principle bears testimony to public ambivalence towards scientific expertise in modern risk societies.

The Wingspread declaration brings attributes that are shared by most of the formulations of the precautionary principle (BRUNEET, 2010, online). The first one understands that existing public policies and regulation are based in insufficient risk assessment. Further, governments are obligated to prevent risk of harm by providing and improving information on such risks and finally government should restrict the use of new technologies until they are proved to be safe.

Some critics of the precautionary principle argue that those defending it are attached to natural or at least to existing technologies, products or goods, even if they are known to be somehow harmful (BURNETT, 2010, on-line). A large number of products people consume or make use broadly around the world would not pass the precautionary principle test, as it is proposed nowadays⁴.

In that sense, how long should we wait until a new technology is introduced? Restricted tests in laboratory are sufficient? Is it possible to prove a new technology safe without empirical testing? Are we willing to take risks in the name of science?

Those are questions yet to be answered, but meanwhile, the precautionary principle has been adopted in most countries legislation and international treaties, mostly in European Union, but also in north and south Americas.

In the United States, the regulation of any biotechnology product is based on its use, and not on the way it is produced. In Europe, although the initial idea was to create a strong regulation and then soften it as the products would show no harm to human health, it has become even stricter in the last years.

⁴ According to Miller and Conko (2000, p. 49), "If precautionary principle had been applied decades ago to innovations such as polio vaccines and antibiotics, regulators might have prevented occasionally serious and sometimes fatal, side effects by delaying or denying approval of those products, but that precaution would have come at the expense of millions of lives lost to infectious diseases".

In mid-2007, the United Nation Food and Agriculture Organization Codex Alimentarius Commission excluded the precautionary principle from its guidelines for food safety. According to Burnett (2010, on-line), the Commission has accepted the United States argument that "the regulatory oversight and risk assessment should focus on the characteristics of the product rather than the molecular or cellular technics used to produce it."

Another problem posed by the flexible definition of the precautionary principle are the trade restrictions of genetically Modified Products, which have caused a number of disputes in the World Trade Organization. According to The United Nations University Report (on line)

Precaution, not science, lies at the heart of much of the public concern about regulation of biotechnology products. In the absence of scientific justification for trade restrictive measures, the WTO will increasingly find itself passing judgment on which regulations are legitimate and which are unnecessary barriers to trade.

Hence, the precautionary principle can, and apparently, has been used as an illegitimate trade restriction or a trade, and not environmental protection, since it can be evoked without a clear or uniform definition⁵.

1.1 Precautionary Principle and risk assessment

What if precautionary principle were applied to itself? That was a question posed by the Social Issues Research Center in Oxford, England. Most possibly, its use would be reduced to minimum levels or, as the research concludes, "we would be forced to abandon it very quickly" (1999, on-line).

⁵ "The flexible definition of the precautionary principle may be its strength, but also its greatest weakness. Several WTO Members have noted in the Committee on Trade and Environment (CTE) that the difficulty of further integrating precaution in the WTO lies in the lack of internationally-agreed definition of the precautionary principle"(United Nations University, On line)

So, if such principle were to be used in a moderate way, supporters should demonstrate that policies aimed at preventing or reducing harm to public health or environment are inadequate and that the precautionary principle would be more efficient in preventing such risks than risk assessment.

According to Goklany (On line) "Both proponents and opponents of the precautionary principle have often argued that it substitutes for the risk analysis". This kind of approach leads the use of the precautionary principle to cause what their critics accuse it of: preventing new technology without any kind of scientific basis.

According to Belt (On line, p.190-1), The Commission of the European Communities

[...] introduced a sharp distinction between risk assessment and risk management, that is, between science and politics. Whereas a prudential approach may be part of (scientific) risk assessment (e.g. by taking into account a pre-defined safety margin in risk evaluation), the application of the PP is held to belong to (political) risk management. Risk management is the preserve of political decision-makers, according to the Commission.

Burnett (2010, on-line) believes that the precautionary principle, in its strong formulation, is not adequate to be the basis for legal decisions since its ambiguity "invite arbitrary legal applications and court ruling concerning when the principle applies and what it requires". Actually, because it is so vague, the author believes that it allows judges to review agencies actions.

Ahteensuu (2004, p. 57) argues that there are different ways to perceive, assess and value risk and lack of certainty.

Some demand the application of sound science criteria as a basis for restricting the production and trade in products that pose a threat to the environment or to human health. Others, in contrast, argue for precautionary measures based on the precautionary principle, which allows policy action to be taken in the absence of full scientific certainty.

The author still states that, although such principle has been used as an excuse for limiting the introduction of new technologies in Europe, few policies of risk management created as much controversy, especially due to the "extreme variability in its interpretation."

Nevertheless, there are those who believe that the criticisms directed at the precautionary principle are not enough for its complete abandonment. The most common criticisms refers to the fact that (i) the precautionary principle is a highly rigid principle that would prevent any kind of change or progress, since, theoretically, any action could lead to catastrophe (AHTEENSUU, 2004, p. 63); and (ii) the formulation of the principle is no scientific.

Sponsors of the Precautionary Principle respond to those criticisms by arguing that the first point is only applicable if the strong (or strict) formulation of the principle is used. Concerning the second point, as the precautionary principle may be considered a decision making strategy, which is, per se, unscientific, and it should be used when risk assessment is nor adequate for the lack of data. (AHTEENSUU, 2004, p. 63-4).

An interesting point of view is presented by Goklany (on line, 2002). He states that the adequate application of the precautionary principle depends on a risk-risk analysis. In other words, "one should compare the risks of adopting the policy against the risks of not adopting it". The author, nevertheless, says that none of the versions of the precautionary principle provides any guidance on how it should be applied if a policy might be foreseen to lead to both positive and negative outcomes where, moreover, both sets of outcomes are uncertain"⁶.

⁶ As an illustration of his point, the Goklany proposes this example: To appreciate the why and wherefore of this result with respect to public health, consider that 800 million people worldwide suffer from hunger and undernourishment, and over 2 billion from malnutrition. As a result, hunger and malnutrition kill over 5 million children annually worldwide. In addition, poor nutritional habits are significant contributors to diseases of affluence (heart disease, strokes, and cancers), which kill almost 20 million more³. To reduce the future toll of hunger, malnutrition, and poor nutritional habits, despite the almost inevitable future increase in human population, means that the quantity and nutritional quality of food must be enhanced. The faster this occurs, the fewer casualties there will be. And GM crops should increase the quantity and nutritional quality of food supplies faster than conventional crops.

Goklany proposes, thus, a new formulation of the precautionary principle that could solve, if not all, some of the issues brought by its application: “Public health and environmental policies should attempt to minimize net risks to public health and environment based on the best available scientific information and their net anticipated costs to society”.

In the same sense, Belt (On line, p. 192), says that as per the strong formulation of the precautionary principle,

the mere prospectus of potentially harmful effects of a new technology is enough to stop its introduction and deployment. But why should the prospect of harmful effects take precedence over the prospect of beneficial effects, quite apart from the inherent likelihood of each of these possibilities? The obvious answer seems to be that such priority is defensible only when the harmful effects are of such magnitude that they carry catastrophe (or, as Jonas would say ‘apocalyptic’) potential.

Hence, it is clear that the precautionary principle does not substitute risk assessment. They are rather different concepts.

2 The Evolution of Biotechnology Laws in Brazil – a Brief Comment

One of the most common criticisms on the regulation of GMO over the world is that such regulation is not really based on the characteristics of the product or the actual risks that such product pose to human health or the environment, but merely on the fact that it was created by using a new technology that involves some kind of genetic manipulation (MILLER et CONKO, 2000, p 47). That criticism seems to make sense when several scientists attest that “the risks associated with the introduction of recombinant DNA-engineered organisms are the same in kind as those associated with unmodified organisms and organisms modified by other methods” (MILLER et CONKO, 2000, p 48).

All around the world, the discussions about the regulation of GMOs take place since the early seventies, but only in the years of 1980 the first

international conventions and treaties were signed. Nevertheless, the conference called Rio 92, which took place in the city of Rio de Janeiro in 1992 enlisted biotechnology and genetically modified organisms in the international agenda. (RIOS, on line).

In fact, in such conference, the Convention on Biological Diversity was signed, and in its article 16.1, provides that

Each Contracting Party, recognizing that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of this Convention, undertakes subject to the provisions of this Article to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment.

Further, article 16 g stipulates:

Each Contracting Party shall, as far as possible and as appropriate:

(...)

(g) Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health;"

Brazil is also one of the parties to the Cartagena Protocol, which was signed in 2000, in Toronto, Canada. Such document foresees that the precautionary principle may be used as basis for the decision making process concerning the trade of genetically modified seeds and crops, in order to prevent accusation by the exporting country on illegitimate barriers to trade.

Concerning the internal regulation, Brazilian Federal Constitution establishes, in its article 225, that everyone has the right to an ecologically equilibrated environment, which is considered a common wealth of the people, and its essential to a sound quality of life. Also, it provides that it is a duty of the government and of the people to defend and preserve the environment for the generations to come. Further, it determines that, in order to enforce such right, government shall preserve the biodiversity and the integrity of the genetic assets of the country and control the entities that engage activities involving research and manipulations of genetic materials. In addition, it is stipulated in same article that authorities shall demand, as provided for by law, a previous study of environmental impact (EIA) for any activity that poses risk to life, quality of life or environment.

It was only in 1995 that Brazilian legislators passed a specific law on Biotechnology, known as the "Biosafety Law", (Law n. 8974/95). Such law defined genetically modified organisms, regulated activities, which involve genetic manipulation and created tools to control the import, test, farming, transportation, trade and discharge of GMOs. It also delegated power to certain authorities to control and issue certificates and authorizations.

In 2005, Law 11.105/05, which is regulated by Decree 5591/05, revoked Law n. 8974/95.

In general terms, the new Law provides, in its article 1o, that the precautionary principle is to be observed for the protection of the environment.

Specifically, such Law regulates entities that engage activities related to biotechnology as defined, being such activities subject to previous authorization of the regulatory organisms created and defined therein. It also requires that sponsors of any entities or projects that engage research or other activities involving biotechnology demand a Certificate of Quality in Biosafety to their sponsored entities. Otherwise, the sponsors are jointly responsible for any adverse effects arisen from the non-compliance with laws and regulations.

Concerning the bureaucratic structure, The National Biosafety Counsel (CNBS), is the superior organ directly responsible for advising the President of the country when it comes to formulation and enforcement of the National Biosafety Policy (PNB). Such organ is also responsible for the analysis, whenever requested by the CTNBio, of economic and national interest aspects of related to the liberation of GMOs and the decisions issued are binding and final. It is important to note that the CNBS is a political, rather than technical organ.

The CTNBio (National Technical Commission for Biosafety) is a technical organ formed by multidisciplinary members with both consulting and deliberative competences. Its scope is to advise and pay technical support to Federal Government in setting the National Biosafety Policies. It is also responsible for issuing technical reports to support authorizations for activities involving biotechnology. It important to note that, according to the Law, the technical decisions of the CTNBio are binding to any authorities concerning the biosafety matters. Therefore, although the authorizations are issued by other organs, such as the Ministry of Agriculture, Ministry of Health, or Ministry of Environment, as the case may be, such authorization is bound by the reports of CTNBio⁷.

Since its creation, CTNBio has issued some authorization for farming and trading GMOs, such as soybean, corn, cotton and vaccines.

It is also stipulated in article 40, the mandatory labelling for GMOs, which are destined to human consumption. This obligation is regulated by Decree n. 4680/03, that determines that every product, which contains more 1% of genetically modified material, must be labelled with a specific symbol. The labelling of products made from animals fed with genetically modified fodder is also mandatory.

As per Cordioly (2008, p. 39), Brazilian regulation on Biotechnology is in accordance with international rules since it is concerned about information, multidisciplinary composition of the regulation authorities

⁷ The controversy on the sole authority of CTNBio to analyze GMOs will be discussed in the next topic.

and a comprehensive view of biosafety, and although it does not bring definition to technical terms, defines good practices in GMOs manipulation.

Cordioli (2008, p. 39-40) asserts that the system foresees social participation in the process of analysis by the use of public hearings; therefore, the author believes it is unlikely that decisions are dissociated from social reality and from people ethical beliefs. Cordioli also believes that Brazilian law may be considered more innovative than others around the world since the analysis by the regulators take into account technical aspects, not only concerning risks to human health and environment, but also comprehends issues related to economic impacts, production and preservation of native or traditional agriculture.

Although the first article of Law 11.105/05 provides that the scope of such law is to stimulate scientific development in biosafety and biotechnology, and the protection of life and human health, Cordioli (*op. cit.* pp. 42-3) affirms that the precautionary principle is the fundamental basis of the whole biosafety system.

It is important to point out that the Cartagena Protocol entered into force in Brazil in 2006, by means of Decree n. 5705/06. It reaffirms the precautionary approach to biotechnology proposed in Rio 92 convention and deals with international trade of GMOs.

3 Brazilian Courts and the Precautionary Principle

According to Ahteensuu (2004, pp. 58-9), the precautionary principle "legitimises government intervention in the liberty of individuals and companies in order to avoid the threat of severe long-term or irreversible damage, even when strict scientific risk assessment cannot be fully complete". "It is not a hypothesis, a theory or a methodological rule. Rather, it is a normative principle for making practical decisions under conditions of scientific uncertainty".

In the same sense, Gomes (2007, p. 253), explains that the precautionary principle arises from a political concern to increase to

maximum levels the consented interference of government in activities that potentially pose risk to the environment or public health.

Hence, one can agree that such principle is not a scientific criterion, and, as such, some standards must be placed for its use by Courts. Otherwise, the legal uncertainty may cause serious adverse effects to economy. Further, as Bim (2012, 0. 132-4) affirms, Courts must not interfere in technical or scientific decisions. That is a reality in the United States (Judicial Deference or Chevron Doctrine). In Brazil, the Superior Justice Court has manifested in Case REsp 1.171.688/DF such ideas: the technical-administrative deference proposes that Courts are to interfere with technical or scientific disputes.

Most of the judicial claims in Brazil regarding biosafety can be enlisted in two groups: (i) those regarding labelling and other consumers issues; and (ii) those, mostly proposed by the Public Attorney's Office, regarding licenses and reports which permit or restrict the cultivation or commercialization of products, including those alleging the unconstitutionality of provisions of Law 11.105/05, specially regarding the authority of CTNBio. Considering the scope of this essay, some court decisions of the second group will be analysed.

There is a relevant discussion on the possibility of CTNBio exempt the presentation of EIA/RIMA, which is provided for in the Federal Constitution. The EIA (Environmental Impact Study) and its respective report (RIMA) are necessary whenever an activity poses risk or is considered potentially dangerous to environment.

The problem is that Law 11.105/05 considers that the CTNBio is entitled to determine whether or not a product or activity is eligible to be exempted from the presentation of the EIA/RIMA, since this Commission determines if such product or activity is potentially risky. Some believe that such power belongs to the National Council of Environment (CONAMA).

This matter is currently object of several lawsuits (including in the Supreme Court). Most of the decisions of inferior Courts determined

that, as per Law 11.105/05, such competence belongs to CTNBio. Notwithstanding, there are decisions asserting for the necessity of EIA/RIMA, even when CTNBio has already issued a favourable technical report on the subject. In such cases, courts determine that other organ is to be consulted, before a GMO is approved for sale or farming.

Law 11.105/05, and its regulating Decree, are very clear about the proceedings to obtain a license and authorization to engage activities involving GMOs. Nevertheless, most of the Public Attorneys who claim, and judges who decide for the necessity of EIA/RIMA despite the favourable report of CTNBio base their claims and decisions on the precautionary principle in its strong formulation. The fact is that there is no, nowadays, juridical stability in court decisions in Brazil, neither concerning the necessary licences and authorities entitled to issue them, nor on the formulation of the precautionary principle applicable to cases.

As an example, we may mention the Public Civil Action no. AC 2000.71.01.000445-6, on genetically modified rice, issued by 4o Federal Regional Tribunal. Judge Carlos Eduardo Thompson Flores Lenz alleges that the mere potential risk is sufficient to take the necessary measures to ensure environment protection and the precautionary principle applies in this case and the EIA/RIMA cannot be exempted. He adds that this exemption is unconstitutional. There are several other examples of this kind of approach as in Case n. TJPR, Ag Instr 0153333-3, this time regarding genetically modified soybeans, Judge Hirose Zeni, of the Justice Court of Parana, decides to apply the precautionary principle to the "concrete case" as claimed by the Public Attorney. Case AC20000100014661, judged in 1o Regional Federal Court also uses the strong formulation of the precautionary principle, in view of a potential irreversible risk to environment posed by the farming of genetically modified soybean.

In a different case, a writ of mandamus imposed the precautionary apprehension of products based on the suspicion that they were GMOs based on the precautionary principle (TJSP AC 280.075-5/3).

In another Public Civil Action (Case no. 1998.34.00.027682-0 DF), this time in 1o Federal Regional Tribunal, on genetically modified soybean (Roundup Ready), Judge Selene Maria de Almeida recognises that the precautionary principle is part of Brazilian internal Legal System, but affirms that legal bounds must apply. Concerning the necessity of the EIA/RIMA, confirms that the specific law about biosafety grants sole authority to CTNBio to issue binding reports on GMOs and that the precautionary principle must not prevent new technology to be used in the country, but only, as provided for by law, not delay necessary measures to protect human health or environment. Judge also affirms that risk assessment is the control instrument used by CTNBio prior to the issuance of its reports. The same judge decided similarly in other cases such as the AC34000276820/DF, also concerning the Roundup Ready Soybean.

As demonstrated, Brazilian Courts do not have a uniform construction of the precautionary principle. As such, inferior Courts might decide differently in similar cases. Such juridical instability generate high costs to those involved in research, production and commercialization of biotechnological products, which, by the end of the day, may increase prices in general.

Uncertainty in the application of the law to the concrete case is an externality that must be compensated by price, or, in a worst-case scenario, modern technology industry would consider too cumbersome to invest in the country.

Conclusions

It is an irrefutable fact that agriculture, in the present days, face some challenges that are not easy to solve: the alternatives to respond to the growing demand for food poses three different possibilities that, although not exclusionary, are considered to be in conflict by some: the continuous use of pesticides (which, ironically, might never pass the precautionary principle application), the organic agriculture, which, if used if broad scale would cause immense amount of native vegetation

to be destroyed and the used of biotechnology in order to improve food production.

Given the aspects analysed in this essay, we may conclude that precautionary principle is widely used around the world and it's a relevant decision making criterion, if it is used in a way not to prevent new technology to be introduced.

In fact, the so-called strong formulation of the principle makes it almost impossible to meet its requirements, since it demands a negative proof on the safety of the GMO, that is, if there is no absolute certainty on the safety of the organism, it shall not be released.

On the other hand, an active approach of the precautionary principle may lead us to a solution based on a risk-risk analysis, and hence one can determine and compare the potentials and actual risks of introducing or not introducing new technology. The precautionary principle is not a scientific formulation, its is a political decision making tool, and must be treated as such.

Concerning Brazilian Law, notwithstanding the quality of the Biosafety Law issued in 2005, the apparent conflict between organs responsible for licenses must be solved, under the penalty of making investments in biotechnology rather unattractive. Consumers must be informed of the nature ad characteristics of any product they consume, not only the genetically modified, and that is also provided for.

Since there is a structured system in biosafety field in Brazil, as foreseen in Federal Constitution, Courts must be bound to that system in order not to create uncertain costs for the industries that certainly are transferred to consumers. Courts must know that the Judiciary is not the place to solve scientific controversies but to apply the law.

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