



## EXAMINING THE BIOSAFETY OF LIVING MODIFIED ORGANISMS FROM A HUMAN RIGHTS PERSPECTIVE

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### ABSTRACT

Biotechnology as a modern-day phenomenon has had profound effects in various fields such as agriculture, health, and the environment. However, there are some concerns among scientists about the potential impacts of products resulting from the technology of living modified organisms (LMOs) on biodiversity and human health. This has led to the development of a set of rules and regulations known as biosafety to ensure the safety of these products under the Cartagena Protocol to the 1992 UN Convention on Biological Diversity. Biosafety can be considered as an approach to protect biodiversity and human health from potential threats while benefiting from the benefits of biotech products. From a human rights perspective, there seems to be a direct link between this field and biosafety, and there are many common concepts in both areas. The article seeks to examine the role of biosafety in human rights protection and examines how human rights can be protected to answer this question. In this analytical study, through studying the literature and primary sources, the role of biosafety in the protection of human rights has been analyzed and criticized from different aspects. The results show that biosafety can be considered a way to balance between different human rights and socio-economic considerations and the way of applying the precautionary principle have an important role in achieving this goal.

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## Introduction

Modern biotechnology can be considered as a creative solution to major problems in a variety of areas, including health and agriculture. Increasing the nutrient quality of crops, increasing crop resistance to harsh, reducing the need for water, fertilizer, labor and less pressure on land and the environment, and ultimately more productivity in the agricultural production process, are some of the results of the great and enormous revolution of biotechnology in agriculture. The findings of researches mention the potential of this technology to solve the problem of food insecurity and malnutrition in developing countries.<sup>1</sup> In the field of the environment, reducing the use of herbicides in the agricultural process and also using lower energy, and waste and even the recycling of waste are some of the effects of using biotech and its recombinant products.<sup>2</sup> So far everything has gone well. But that is not the end of the matter. Concerns are raised about the possibility of resistance to herbicides, the creation of weeds, and most importantly, horizontal gene transfer through pollination. From the critics' point of view, this poses a threat to biodiversity and possible causes of genetic contamination. Opponents of the use of LMOs also emphasize the potential risks of transgenic products to human health and the adverse effects such as allergies, poisoning, and antibiotic resistance. However, there is no consensus on these effects,<sup>3</sup> and advocates of using living modified organisms believe that there is no credible evidence on the threat of LMOs to the environment and health.

The U.S. Food and Drug Administration (FDA), the U.S. Environmental Protection Agency (EPA), and the U.S. Department of Agriculture (USDA) ensure that GMOs are among them.<sup>4</sup> Therefore, due to the uncertainty regarding the use or non-use of these products on the

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1 . Alexander F McCalla, Lynn R Brown, 'Feeding the Developing World in the Next Millennium: A Question of Science?' (Agricultural Biotechnology and the Poor: Proceedings of an International Conference, Washington DC, 21-22 October 1999) 35.

2 . David Zilberman, Tim G Holland and Itai Trilnick, 'Agricultural GMOs—What We Know and Where Scientists Disagree' (2018) 10 Sustainability 1, 5.

3 . Angelika Hilbeck, Rosa Binimelis, Nicolas Defarge, Ricarda Steinbrecher, Andras Szekacs, Fern Wickson, Michael N. Antoniou, Philip L. Bereano, Ethel Ann Clark, Michael Hansen, Eva Novotny, Jack A Heinemann, Hartmut Meyer, Vandana Shiva, Brian Wynne, 'No Scientific Consensus on GMO Safety' (2015) 27 Environmental Sciences Europe 1, 1.

4 . US Food and Drug Administration, 'How GMOs Are Regulated in the United States' (2022); available at: <https://www.fda>.



one hand, as well as the lack of scientific certainty about the potential adverse effects of these products on the other hand, a variety of measures, guidelines, rules, and regulations have been developed for the use of these benefits, called Biosafety. The Cartagena Protocol on Biosafety has been developed based on the use, transportation, transit, export, and import of these products. These rules and regulations rely on the key principle of the precautionary principle, which implies that scientific uncertainty does not preclude the risk of a phenomenon from taking precautionary measures. Accordingly, biosafety is based on measures such as risk assessment and management that monitor the safety of these products before, during, and after the release of transgenic organisms. The precautionary principle is the heart and the axis of biosafety. According to the precautionary principle of biosafety, the product must be proven to be safe and, merely lack of certainty about the risk of these products to the environment and human health is not enough to authorize the use and release of these products. This conception of the precautionary principle in Article 10(6) of the Cartagena Protocol is inferred.

The most important effect of this principle is that the burden of proving that transgenic organisms are harmless lies with the one who claims that they are harmless.<sup>1</sup> However, from a human rights perspective, different views on the use or non-use of transgenic products can be seen as two different approaches to protect two sets of human rights. Protecting the right to food and development versus protecting the right to health and the right to the environment. Therefore, accepting any of these different views can be considered as a threat to the front side set of human rights. The question now is whether biosafety is capable of integrating diverse views on transgenic products? Can it be seen as a solution to balance human rights in different ways? To be more precise, what kind of approach to biosafety can guarantee compliance with these rights? It is important to examine the relationship between recombinant products and human rights because explaining this relationship can be effective in the humanistic goals of environmental law.

## 1. Right to Food and the Role of LMOs

The concept of right to food is generally considered to be part of the right to life at a standard level of living,<sup>2</sup> and therefore LMOs are a double-edged sword and determine how to properly deal with these products at the discretion of their potential effects on these standards. Such an approach contradicts any interpretation that restricts the right to food to the mere intake of calories, protein, and minerals needed by the body.<sup>3</sup>

In general, modern definitions of human rights are based on the concept of human dignity, and recent generations of human rights can be defined as generations based on dignity, and the right to food must be achieved by observing this important component. Accordingly, the mere provision of food does not comply with human dignity and the provision of this important right.

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gov/food/agricultural-biotechnology/how-gmos-are-regulated-united-states

1 . Abdelnaser Zeyad Hayajneh, 'Civil Liability for Environmental Damage: A Comparative Study Between Jordanian and English Legal Systems' (DPhil thesis, Newcastle University 2004) 22.

2 . Asbjørn Eide, Catarina Krause and Allan Rosas, *Economic, Social and Cultural Rights: A Textbook* (Kluwer Academic Publishers 1995) 119.

3 . FAO, *Right to Food, Making It Happen; Progress and Learned Lessons through Implementation* (FAO 2011) 3.



Therefore, the mere definition of the right to food as freedom from hunger is inconsistent with such an approach and the concept of dignity needs to be taken into account in this definition.

The role of LMOs in maintaining food security and subsequently protecting food rights is significant. Experts believe that the future is promising for LMO crops to overcome food shortages and create a sustainable food chain.<sup>1</sup> The results of scientific research emphasize the efficacy of adopting modern biotechnology to increase the quantity and quality of food and that this improvement in quality and quantity may be considered as the realization of the objectives of the right to food as described in the documents above mentioned.<sup>2</sup>

Of course, it should not be overstated about the abilities of LMOs. Even though certainly no one can consider crop biotechnology and its recombinant crops as a miracle survivor of widespread social, economic, and environmental crises, major analysts emphasize the effective role of these crops in future food security strategies.<sup>3</sup> Based on such an approach as well as scientific data, the use of transgenic seeds can be considered a way of protecting the right to food, a right that has been explicitly emphasized in international instruments such as article 25 of UDHR and article 11 of ICESCR.

On the other hand, however, the potential danger of these organisms to food security and the right to food should not be ignored. Accordingly, the theory that the relationship between food security and transgenics is merely a positive one is hardly in doubt. Nor should the risk be ignored that this technology would act like a boomerang by reducing biodiversity and disrupting the food chain and subsequently reducing food quality.<sup>4</sup>

## 2. Right to the Environment and the Role of LMOs

The concept of the right to the environment has been raised by the third generation of human rights as solidarity rights and is now accepted by many countries around the world, notwithstanding doubts about the recognition of the third generation of human rights. Neither the European Convention on Human Rights nor the European Social Charter guarantee any degree of protection for the environment.<sup>5</sup> However, they accepted some other human rights (to life, private life, and family, property, information, etc.) as supporting environmental rights.<sup>6</sup> Despite the difficulty of providing a precise definition of the right to environment, in a comprehensive definition, it can be regarded as “a human right that protects human quality as well as the destruction of the biosphere and nature”.<sup>7</sup>

Whatever the definition, it seems that the core of the right to environmental protection is the protection of the human, animal, and plant environment. The important point is that the most significant threats from LMO products is two different elements of environment and biodiversity. That is why Article 19 of the Convention on Biological Diversity forms the basis of the

1 . Oliver Melvin J, ‘Why We Need GMO Crops in Agriculture’ (2014) 111 Missouri Medicine 492, 506.

2 . Mala Trivedi, Rachana Singh, Manish Shukl, Rajesh Kumar Tiwari, ‘GMO and Food Security’, in Omkar (ed) Ecofriendly Pest Management for Food Security (Elsevier Inco 2016) 706.

3 . Matin Qaim and Shahzad Kouser, ‘Genetically Modified Crops and Food Security’ (2013) 8 PLOS ONE 1, 7.

4 . Rashmi Patowary, ‘Scrutinizing the Impact of GMOs Through the Prism of Human Rights’ (2014) 7 OIDA International Journal of Sustainable Development 79, 81.

5 . Council of Europe, Manual on Human Rights and the Environment (second edition, Council of Europe Publishing 2012) 7.

6 . Ibid, 17-22.

7 . Ali Mashhadi, The Right to Environment (Iranian-French Model) (Mizan Publication 2013) 55. [In Persian]



Cartagena Protocol and this Protocol is also concerned with protecting the environment taking into account the threats posed by LMOs to human health. Opponents argue that the main danger posed by the LMOs which threatens the environment is the loss of biodiversity.<sup>1</sup> Contamination of major habitats, plant sites, and gene centers can be too catastrophic by destroying the plant's biodiversity. On the other hand, pest resistance to transgenic plants is also a potential hazard and the pest may also sometimes resist the LMO plant itself.<sup>2</sup>

Genetic contamination is also one of the dangers that transgenic living organisms may have to the environment. Genetic contamination means transferring the LMO gene to the natural plant and producing its traits in the recent plant. This genetic contamination is done through horizontal gene transfer, that means translocation and transfer of genes (via transformation, transduction, and conjugation) which may cause new characteristics in the receiving organism and, as a consequence, may ultimately lead to potential damage to the environment.<sup>3</sup>

Undoubtedly, the above reasons can be considered as the main motivation for the creation of Article 19 of the Convention on Biological Diversity. Genetic contamination can significantly jeopardize biodiversity and may limit farmers' scope of choice and the seed selection cycle. The saturation of the market with transgenic seeds and the scarcity of organic seeds limit the farmers' right to choose the required seeds. Regardless of the economic monopoly for large companies such as Monsanto and their strategic dominance over food security, undoubtedly reducing biodiversity and reducing the diversity of selected seeds for farmers are undesirable effects the need for control and management of which is obvious.

It seems that the balance between the possible and potential side effects of transgenic seeds is in adopting an approach that does not simultaneously protect the environment, the right to development, and food. In fact, irrational and extremist precaution prevents the combination of conflicting rights. The use of appropriate methods for cultivation, such as cultivation on special farms and under proper supervision, with a rational approach, can be helpful in this regard. We must keep in mind that the precautionary principle, in any case, has a pessimistic and not necessarily a realistic basis.

### 3. Right to Development and Role of LMOs

Development should be considered as a multidimensional concept that includes progress in various political, economic, and social areas. The Declaration of the United Nations General Assembly on December 4, 1986 stated the right to development as follows in Art. 1:

*“The right to development is an inalienable human right by virtue of which every human person and all peoples are entitled to participate in, contribute to, and enjoy economic, social, cultural and political development, in which all human rights and fundamental freedoms can be fully realized.”*

1 . Thomas Bøhn, 'Invasion of exotic species: Lessons for GMOs?', in Terje Traavik and Lim Li Ching (eds), *Biosafety First: Holistic Approaches to Risk and Uncertainty in Genetic Engineering and Genetically Modified Organisms* (Tapir Academic Press 2007) 200.

2 . Salehi Jozani, Gholamreza, Tohidfar, Masoud and Sadeghi Akram, *Biosafety of Transgenic Crops* (Modir-e-Fallah Publication 2011) 45. [In Persian]

3 . Dhan Prakash, Sonika Verma, Ranjana Bhatia, Bhupendra N Tiwary, 'Risks and Precautions of Genetically Modified Organisms' (2011) 2011 International Scholarly Research Network 1, 2.



The economic and developmental effects of transgenic organisms are the main motivations to use these crops and it can be found in economic and development-oriented results of cultivating the LMOs.

Studies emphasize the usefulness of these products for farmers and consumers. For example, the positive effects of products such as BTs on reducing poverty and increasing income can be considered as an incentive to use these seeds.<sup>1</sup> For the same reasons in 2008, LMO crops were being grown on 125 million hectares in 25 countries. The countries which have the biggest share of the LMO crop area were the United States (50%), Argentina (17%), Brazil (13%), India (6%), Canada (6%), and China (3%)<sup>2</sup> of which approximately 55 million hectares were in developing countries and 70 million hectares in developed countries. Statistics in 2017 marked a significant change: first, an increase of about 64 million hectares over nine years, and secondly, a shift in the balance between developing and developed countries. 189/8 Million hectares of land were under transgenic cultivation while 100/6 million hectares of them were in developing countries and 89/2 of them were in developed ones.<sup>3</sup>

Statistics also demonstrate that between 1996 and 2016, a total of \$ 186.1 billion was generated from planting these crops, and the revenue from these crops in 2016 totaled \$ 18.2 billion. Significantly, the developing countries share \$ 10.2 billion of total revenue in 2016. These statistics can well illustrate why there is a significant trend, especially in developing countries, for the use of agricultural biotechnology.<sup>4</sup>

Development is a necessity to eradicate or reduce poverty, and the use of transgenic crops in developing and poor countries can be effective in achieving this. It is important to note that most poor economies are weak and are usually based on agriculture and seventy-five percent of the world poor are smallholder farmers or rural workers, and the use of LMO seeds can play an important role in increasing income and development in these countries.<sup>5</sup>

As a result, the figures show well that development is the main driving force, especially in developing countries in increasing and utilization of LMOs. Therefore, the role of public opinion especially in rural and agricultural societies in claiming the right to development is a significant factor in the enthusiasm of these countries to increase transgenic agriculture. In fact, we have to admit that so far, according to available statistics, the positive effects of these technologies on the development and improvement of the lives of people in developing countries have been more than the negative effects. While it is not clear what percentage of biodiversity loss is related to the use of these technologies, it is generally difficult to assess the extent of such damage.

#### 4. Right to Health and the Role of LMOs

The right to health as a human right is fully established in international law<sup>6</sup> in several international documents such as the Universal Declaration of Human Rights (1948), the International

1 . Matin Qaim, *The Economics of Genetically Modified Crops* (2009) 1 *The Annual Review of Resource Economics* 665, 685.

2 . International Service for the Acquisition of Agricultural Applications, *Global Status of Commercialized Biotech/GM Crops: 2008* (ISAAA 2008) 11.

3 . International Service for the Acquisition of Agricultural Applications, *Global Status of Commercialized Biotech/GM Crops in 2017: Biotech Crop Adoption Surges as Economic Benefits Accumulate in 22 Years* (ISAAA 2017) 4.

4 . *Ibid*, 106.

5 . Qaim (no 18) 673.

6 . World Health Organization, *Advancing the Right to Health: The Vital Role of Law* (World Health Organization 2017) 7.



Covenant on Economic, Social and Cultural Rights (ICESCR) (1966), and several international treaties of human rights law has recognized it including article 24 of the Convention on the Rights of the Child (1989). Among others, article 12(1) of (ICESCR) states that:

*“The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health”.*

The above definition of health does not appear to be a comprehensive one. It is for certain that the concept of physical and mental health and its standards is vague and incomprehensible, and it is necessary to specify precisely what these standards include.

An appropriate definition of this right can include a number of factors that ensure a healthy life which in the Committee on Economic, Social and Cultural Rights view include a wide range of factors related to water, food, environment, and socio-economic issues.<sup>1</sup> Accordingly, the right to health has a broader meaning, and in this respect a more complex relationship between the transgenic crops and the right is conceivable. Therefore, it seems unlikely that a one-sided approach can be put forward and merely hypothesized. However, given the more precise definitions, the quality and quantity of food that has always been claimed by transgenic crop supporters should be considered, including factors affecting the protection of health. Thus, this approach can be seen as a dichotomy concerning the transgenic crops and the aforementioned right and can justify the opposition to or approval of either group of supporters and opponents of the use of the transgenic in the context of defending the right to health. This claim has been repeatedly made by both groups before.

On the one hand, improving the quality of food and its nutritional richness has been proposed as an important factor in the field of health, and art. 24 of the Convention on the Rights of the Child also addresses the issue of proper nutrition and its relationship with children’s health. In this respect, the scales are heavier in favor of the supporters of LMOs, and the claim that food products are richer in minerals needed by the body with the help of LMOs can be proven.

However, as mentioned earlier, potential health risks have been among the claims of opponents of these products. Potential risks of diseases such as cancer, gynecological diseases, allergies, etc. The veracity of such a claim has always been denied by the other side. Accordingly, human rights are facing a difficult dilemma. How to take advantage of the benefits and facilities of this new technology to strengthen the right to health and at the same time protect human beings from the potential (but worrying and frightening) dangers of this technology.

## 5. The Relationship Between Biosafety and Human Rights

Although the Cartagena Protocol is an environmental document, it still has significant human rights values. The preamble of this protocol emphasizes that “modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health”. In general, the Cartagena Protocol is a way to use biotechnology while protecting the health and the environment. From a human rights standpoint, the document seeks a solution to the right to food, the right to development, the right to health, and the right to

1 . UN Committee on Economic, Social and Cultural Rights, ‘General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12 of the Covenant)’ (2000) E/C.12/2000/4, para. 4.



the environment. However, there are significant problems with implementation. The first is that the potential dangers of these organisms to health and the environment or life are not entirely certain. Research has not been able to pinpoint the exact reasons for these effects. On the other hand, despite the uncertainty, there will be significant damage to the environment and health if the idea comes true that LMO's are harmful. Therefore, the decision on the release and implementation of biosafety regulations in this regard faces a major challenge as to what level of risk should be considered serious and what level of risk is acceptable to the community from a human rights perspective. Which one is more important, development and the right to food or health and the environment? In other words, what is the primacy of other rights? It is also difficult to answer the question of which rights can be prioritized?

Different communities appear to have adopted different approaches in this regard. A notable example is the United States. It is the largest producer of transgenic products in the world and has not yet joined the Cartagena Protocol. US law seems to have shown a positive approach to increasing the cultivation of transgenic crops. The absence of any federal law banning or restricting the cultivation of these crops indicates that the country's legislature is willing to make the most of the economic benefits of this technology. The above approach, on the other hand, has caused the domestic markets of this country to face a lot of consumer products based on this technology and to occupy about 75% of the processed products market.<sup>1</sup> From a human rights perspective, such an approach can be attributed to the insignificance of ESCRs in the United States. Clearly, the US approach to human rights is almost entirely civil and political, and ESCRs are often subjugated by economic considerations. In fact, the United States has not recognized these rights as real human rights for decades,<sup>2</sup> and these capitalist-based economic considerations can be considered as the basis for such an approach.

Another example is Argentina, the third-largest producer of these products in the world after the US and Brazil.<sup>3</sup> It signed the Cartagena Protocol in 2000 but has not ratified it so far. However, there are no significant restrictions on the release of these organisms, whether in enclosed or non-enclosed environments. It may be attributed to the country's significant profit from the production of these products. However, the strong influence of US policies on these two countries cannot be ignored. Statistics clearly show the effective role of transgenic agriculture in the Argentine economy. Billions of dollars in economic benefits, along with about one million jobs between 1996 and 2006, provide a good incentive to develop the cultivation of these crops in the country.<sup>4</sup> The statistics well illustrate the reason for the development of transgenic use in Argentine agriculture.

Contrarily, the EU approach is the most interesting one. The cultivation of LMOs in the EU is limited. According to EU regulations, its members must restrict or prohibit the cultivation of LMOs plants on the EU declaration. Regulation No. 1829/2003 prohibits placing on the EU

1 . Alice Yuen-Ting Wong, Albert Wai-Kit Chan, 'Genetically Modified Foods in China and the United States: A Primer of Regulation and Intellectual Property Protection' (2016) 5 Food Science and Human Wellness 124, 130.

2 . Gillian MacNaughton, Mariah McGill, 'Economic and Social Rights in the United States: Implementation Without Ratification' (2012) 4 Northeastern University Law Journal 365, 406.

3 . International Service for the Acquisition of Agricultural Applications (no 20) 5.

4 . Moisés Burachik, 'Experience from Use of GMOs in Argentinian Agriculture, Economy, and Environment' (2010) 27 New Biotechnology 588, 591.





market a GMO for food use, or a portion of food containing or consisting of GMOs or food products produced “from” GMOs unless an authorization is granted. The EU’s strict approach in this regard is due to the way the precautionary principle is implemented in EU regulations. The precautionary principle is one of the most important and emphasized principles in article 191 of the consolidated version of the Treaty on the Functioning of the European Union. The EU is so strict that even in the case of C-442/09: *Karl Heinz Bablok and Others v. Freistaat Bayern*, the EU Court ruled that even in the event of unintentional contamination of honey and pollen with a transgenic gene, special permissions are required to continue the work.

In general, the precautionary principle can be considered a tool for the protection of human rights. This is a matter endorsed by the European Court of Human Rights. In addition to the European Convention on Human Rights in its jurisprudence, the *Tatar v. Romania* case is an example of the Court’s emphasis on the use of precaution in the protection of human rights.<sup>1</sup> Therefore, it is clear that the approaches of different countries are not the same, as this difference seems to be strongly influenced by economic, cultural, and social conditions. It is the condition that determines the conflict between different rights and interests. Which one would you prefer?

However, protecting one group of human rights should not be in a way that deprives people of the interests of other groups. So, biosafety seems to be the answer to this, and the preamble of the Cartagena Protocol on Biotechnology reflects that. The question now is what biosafety processes can be a determinant in this volatile and buoyant situation. Do biosafety rules have a determining factor in determining what approach should be used in each country? The necessary explanation that the basic rule of biosafety is the precautionary principle that implies that the scientific uncertainty about the potential dangers of a phenomenon does not preclude the appropriate decision being made. It also forms the heart of biological safety risk assessment, which, according to the precautionary principle, puts the burden of the proof about the product’s safety on its operator. The question now becomes a bit more complex. How can biosafety principles based on the precautionary principle of different seemingly inconsistent rights be safeguarded?

Part of this answer should be sought in the social approach and understanding of the precautionary principle. The precautionary concept and scientific uncertainty regarding the scientific findings in the field of transgenic products have got widespread. Although the Cartagena Protocol and the Codex Alimentarius can be helpful, however, these concepts must be defined and applied in the cultural, social, and economic contexts of any society. Accordingly, it may be necessary to define the precautionary principle and concepts such as scientific certainty and the level of risk tolerance. Accordingly, any community with a biosafety approach should decide on this field of biosafety<sup>2</sup> and such definition can be a key to solve the problem of how we can integrate these rights and with the social needs and conditions.

## 6. Socio-Economic Considerations

Article 26 of The Cartagena Protocol provides for the possibility of taking social and economic considerations into account in the risk assessment process. Accordingly, applying the socio-economic

1 . Council of Europe (no 12) 155.

2 . Janet Elizabeth Blake, Komail Sadeghi, ‘Study of Precautionary Principle in the Light of Biosafety Act’ (2019) 9 *Bioethics Journal* 87, 98. [In Persian]



conomic considerations during risk assessment can include potential harm of these organisms to agriculture and the economies of the communities resulting from the reduction of biodiversity. Reductions may pose a pervasive risk not only based on product characteristics but also according to economic and social conditions. Such an approach may be considered as a step toward the good governance of modern biotechnology.<sup>1</sup>

Social and cultural considerations can be discussed from two approaches in this area. The first is a pragmatic approach and the second is a human rights-based approach. From a pragmatic point of view, paying attention to indigenous biological cultural values can provide an understanding of how to manage and protect the environment in different communities. Paying attention to the species and plants that are sacred and respected by the communities as well as the traditions that are somehow related to natural resources is part of the environmental management process.<sup>2</sup> From a human rights perspective, this is seen as a protection of the right to identity. The right to identify as a kind of collective right implies the identity of various values such as cultural values as mentioned in art. 29 of the Convention on the Rights of the Child, and also protection of cultural rights as recognized in art. 5 of the 2001 UNESCO Declaration on Cultural Diversity.

The importance of social and economic considerations in the risk assessment and management process is not hidden from anyone. Cultural and economic components are influenced by decisions in this area on the one hand, and on the other hand, these considerations may affect the final decision on the use of transgenic products. In fact, the insistence of developing countries on the inclusion of socio-economic considerations in the preliminary negotiations of the Cartagena Protocol stems from these issues.<sup>3</sup>

In practice, most developing country members of the Cartagena Protocol have taken this consideration into account in the risk assessment process. For example, art. 30 of the Burkina Faso Biosafety Act emphasizes that licensing for LMOs is subject to certain conditions, including proving that the LMO “ne nuit pas à l’environnement socio-économique” (does not harm the socio-economic environment). Paragraph 3 of art. 53 of the Colombian Biosafety Act explicitly speaks about the dangers of food security and considers it necessary in the risk assessment process. Paragraph 1 of art. 2 and art. 63 of the Mali Biosafety Act have a significant approach to social and economic considerations and even the liabilities arising from them and include the following conditions:

*Article 2 (1): “Socio-economic impact’ means the direct or indirect effects of a genetically modified organism or a product derived from a genetically modified organism on the economy or socio-cultural conditions or the lifestyle or systems or techniques of knowledge of one or more indigenous communities, including the economy of the country.*

1 . Lindsey Fransen, Antonio La Vina, Fabian Dayrit, Loraine Gatlabayan, Dwi Andres Santosa, Soeryo Adiwbowo, Integrating Socio-Economic Considerations into Biosafety Decisions: The Role of Public Participation (World Resources Institute 2005) 1.

2 . Bas Verschuuren, ‘Integrating Biocultural Values in Nature Conservation: Perceptions of Culturally Significant Sites and Species in Adaptive Management’, in Gloria Pungetti, Gonzalo Oviedo and Della Hooke (eds), Sacred Species and Sites: Advances in Biocultural Conservation (CUP 2012) 233.

3 . Ruth Mackenzie, Françoise Burhenne-Guilmin, Antonio G.M. La Viña, Jacob D. Werksman, An Explanatory Guide to the Cartagena Protocol on Biosafety (International Union for Conservation of Nature and Natural Resources and FIELD 2003) 163.



*Article 63: “Liability and redress will also extend to socio-economic considerations:*  
- *nuisances and damage caused directly or indirectly by the genetically modified organism or the product derived from a genetically modified organism to the economy;*  
- *social and cultural conditions, including negative effects on lifestyles, traditional knowledge or technologies of one or more communities;*  
- *damage and loss caused by public disturbances caused by the genetically modified organism or the product of a genetically modified organism;*  
- *total or partial destruction of industrial or agricultural production systems, loss of crops, soil contamination;*  
- *damage to biological diversity, the economy of a region and any other indirect damage and interests.”*

These are some of the issues related to economic and social considerations that can be seen in food security concerns from the effects of transgenic products. Therefore, considering the mechanism of Article 26 of the Cartagena Protocol can be considered an appropriate approach to safeguarding human rights, and it seems that this issue has been addressed primarily by developing countries based on these concerns. But we must notice that the ability to use this mechanism is restricted and it looks like that it cannot be removed from its domain. A strict interpretation of the text in the Cartagena Protocol seems to show a narrow implementation scope that is limited to effects on biodiversity, and not the broader human rights implications (both potentially positive and negative). However, countries can and have included socio-economic considerations in their decision-making utilizing national legislation.<sup>1</sup>

## **7. The Precautionary Principle and Risk Assessment**

The precautionary principle is defined to be “taking preventive action in the face of uncertainty; shifting the burden of proof to the proponents of an activity; exploring a wide range of alternatives to possibly harmful actions, and increasing public participation in decision making”.<sup>2</sup> Risk assessment and its management are at the heart of the rules on biosafety and are sometimes the most important manifestation of the implementation of the environmental precautionary principle in the Cartagena Protocol.<sup>3</sup>

Risk assessment based on the precautionary principle seems to be the first way to safeguard people’s rights. Making a risk assessment based on the precautionary principle can also protect the environment and human health while developing biotechnology, and thus the precautionary principle can weigh the scales positively in favor of the environment and human health. Apply-

1 . Daniela Horna, Patricia Zambrano and Jose Falck-Zepeda (eds), *Socioeconomic Considerations in Biosafety Decisionmaking: Methods and Implementation* (International Food Policy Research Institute 2013) 9.

2 . David Kriebel, Joel Tickner, Paul Epstein, John Lemons, Richard Levins, Edward L. Loechler, Margaret Quinn, Ruthann Rudel, Ted Schettler, Michael Stoto, ‘The Precautionary Principle in Environmental Science’ (Commentaries) (2001) 109 *Environmental Health Perspectives* 871, 871.

3 . Blake, Sadeghi (no 28) 92.



ing this principle in the risk assessment process can be seen as safeguarding the right to health and the right to a healthy environment. Of course, it is necessary to apply this principle to the extent that it does not contradict the main purpose of these rules and the Carthage Protocol, which is the sustainable development of biotechnology.<sup>1</sup> But how we must balance the different rights in this way and in such a way that none of these rights is violated and in case of conflict, what is the way to identify the priority between different rights?

Obviously, what is stated in the Cartagena Protocol on the need to apply the precautionary principle in the article is quite vague. On the one hand, the appendices to the protocol also state precisely how strict a precautionary risk assessment should be. What the authors maintain is a balance in respect for the diverse rights of people in the field of transgenic crop cultivation; put it another way, how the standards for risk assessment are set and standardized based on the precautionary principle. The concepts of risk, scientific certainty, and uncertainty have considerable flexibility, and this flexibility provides the conditions for considering economic and social conditions. Internal laws and frameworks appear to have the capacity to provide some flexibility and a range of interpretations to the extent that they do not depart from the objectives of the Protocol. The Protocol also addresses the specific conditions of developing countries in how they implement the Protocol, which confirms that its drafters have regard to the specific conditions of developing countries and the possibility of adopting measures to address them and have been aware of the conformity of the provisions of the Protocol with their particular requirements.

## Conclusion

Biosafety can be seen as a solution to integrate multiple human rights and to balance the demands underlying these rights. Biosafety can, therefore, be a scientific approach based on risk assessment and management and on the precautionary principle, while also relying on related social values and necessities. The generality and comprehensiveness of the concept of precautionary principle imply that there is considerable flexibility in defining and applying this principle, and it seems that this flexibility is itself an appropriate capacity to consider and evaluate human rights values and considerations in the process of risk assessment and management to protect these rights. In this regard, it seems prudent to provide precise definitions of the precautionary principle in every society and in national biosafety rules and frameworks to protect human rights. Providing a definition and scope of this principle within national frameworks and regulations can guarantee its implementation as well as respect for human rights. The precautionary principle is the heart of biosafety regulations and plays the axis role in them, and any definition of it can have an impact on the fate of human rights related to the right to food, health, development, and environment. In fact, the positive impact of the precautionary principle on the protection of human rights is an issue that has also been endorsed in the case-law of the European Court of Human Rights in *Taskin and others v. Turkey* and also in *Tatar v. Romania*. In the end, it should not be overlooked that the relationship between human rights and biosafety can

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1 . Komail Sadeghi, 'The Legal Dimensions of Biosafety: Meet Iran as a Case Study' (MA Dissertation, Shahid Beheshti University 2016) 33. [In Persian]



be considered as the starting point for incorporating and introducing the precautionary principle from biosafety and the environmental law to the scope of human rights. In fact, it is not unlikely that in the near future we will see the manifestation of the effects of the precautionary principle in the field of human rights.



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