How Far is the Precautionary Principle Considered in the Benefits of Genetically Modified Organisms World Wide?

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Abstract

It has been years since the human kind first started to advance their life qualities. Humans have evolved all kind of aspects in their lives such as economically, socially, technologically, and scientifically. If we are to integrate between technology and science, we would end up with one of the leading aspect in human life that is biotechnology. From the early stages of using organisms or molecular analogues into certain products or services, biotechnology has taken us into a very different level of new nature insertion that is the Genetically Modified Organisms (GMO). GMO is an organism (human, animals, and plants) or microorganism that is genetically engineered, in order to create new and inheritable characteristic. Because of its direct impact upon human and environment health, the implementation of the precautionary principle is ought to and has been able to settle worries that come from countries across the world. Either GMO is considered as a scientific or trading premise, both Cartegana Protocol on Biosafety and the Sanitary and Phytosanitary Measurement from the World Trade Organization have ensured the safety of those products. Despite all the regulations, nowadays, there are still a lot part of countries that banned the usage of GMOs domestically. These actions have left law experts and international organizations wonder how far the countries consider the binding of GMO regulations and its precautionary principle.

A. Introduction

Since the beginning of early human civilization, biotechnology has become a part of human activities, aiming on improving the quality of life. As time goes by, traditional biotechnology such as using yeast to make alcohol has evolved into a modern way of using genetically engineered (GE) substance. Those products of GE are called the Genetically Modified Organisms (GMO) under the regulations of Cartegana Protocol on Biosafety (CPB). GMO is an organism (human, animals, and plants) or microorganism that is genetically engineered, in order to create new and inheritable characteristic.1

It only became a problem when GMO are commercialized below the regulation of the Sanitary and Phytosanitary (SPS) Agreement. Nations do not trust the resemblance of SPS Agreement standard with the CPB regarding to GMO

products. Thus, the Precautionary Principle (PP) came through as a link between SPS Agreement and CPB with the goal of minimizing human health and environmental risks. Despite of that, there are still most nations who prohibit the cultivation of GMO benefits commercially such as Germany, Italy, and Poland. Due to that, the purpose of this research is to understand the implementation of PP by the nations regarding to the benefits of GMO according to CPB and SPS Agreement and the establishment in Indonesia.

This research uses the normative legal research with secondary type sources consisting of primary, secondary, and tertiary material of legal source. The collecting method of the research data is through literature-study techniques. Afterwards, the providing data would be process by a law comparison among countries to have a proportion of precautionary principle adoptions. The result stated that in order to regulate the GMOs, CPB has few requirements that have to be fulfilled for export-import mechanisms such as Advanced Informed Agreement, Simple System of Agriculture Commodity, Biosafety Clearing House, Export Documentation, risk assessment and management. In the other hand, SPS Agreement regulates the needed standards for GMO products that are Codex Alimentarius, World Organization for Animal Health (OIE), and International Plant Protection Convention (IPPC). As for implementing PP, nations implement by adopting through their national law; Korea (still adapting), Brazil (CTNBio and estudio de impacto ambiental), Germany (The Vorsorgeprinzip), and Indonesia (environment management act, government regulations No. 27 year 2012, and government regulations No. 5 year 2012).

Based on the urgency acknowledged above, it is very clear that the importance of this matter should be considered in order to provide a clearer and better understanding on the practice of implementing PP’s role as the international environmental law’s principle between states, particularly in the benefits of GMO.

B. Precautionary Principle and the GMOs
   1. Precautionary Principle
      On the early year of 1970, the precautionary principle was recognized from a German fundamental environmental law principle known as the vorsorgetprinzip. It is now adopted into many policies that connect with environmental cases in German such as acidic rain, global warming, and the North Sea pollution. And then, the precautionary principle was introduced in the 1987 Ministerial Declaration of the Second Conference on the Protection of the North Sea through the amendment of the Maastricht Treaty on the European Union.

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Internationally, the precautionary principle was first introduced on the 1984, through the First International Conference on Protection of the North Sea, which is followed by number of conventions and international treaties, among them are the Bergen declaration on sustainable development, the Maastricht Treaty on the European Union, the Barcelona Convention, and the Global Climate Change Convention. Nowadays, the precautionary principle has enrolled in international policies that relate with high risk international issues whereas the science is still in doubt or as sustainable development national planning.

Definitions of precautionary principle have never sought the light of day, although it is clearly explained in the 15th principle of Rio Declaration which stated:

“Where there are threats of serious or irreversible environmental damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation.”

The term of “measures” is not particularly mentioned, but mainly accepted as governments’ actions in using their authorities to lack or give provisions as to consider the developments or activities of its’ countries’ environmental issues. Mainly, the precautionary principle is just a form of a “careful” nature. While specifically, precautionary principle is an environmental-risk origin principle that acts as a standard to prevent serious cases relating to human and environmental health, based on uncertainty or science presumption upon negative circumstances.

Precautionary principle aims to avoid case in a negative possibility which is addressed as ruin problems. Ruin problems can be explained as an absolute more that 0% chance of irreversible risks. One of the real examples of an irreversible risk is extinction of a species. The component of precautions consists of:

a. Having a purpose, such as establishing an intended kind of agriculture or seed breeding.

b. Considering and re-evaluating dangerous practice alternatives.

c. Transferring burden of proof to the financially responsible which comes with the responsibility of evaluating, understanding, researches, information, and professionalism.

d. Evolving a democratic and open procedure that allows a whole decision making methods and criteria.

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4 Joel Tickner, loc.cit.
2. What is the GMO?
Genetically Modified Organisms (GMO) are living organisms that experienced changes of their nature and characteristics using modern science technology which studies the inheritance of an organism’s nature or characteristic to another that creates a new nature. Genetic engineering can be understood as changes of an animal’s or plant’s nature to develop new natures that are intended by humans. For example, a pest-resistant gene from a certain bacteria is inserted to a plant. Due to that, the plant embraces that same resistant. From that example, we can identify that GMO’s are not only possible between the same species, but also different species which are called as transgenic.8

a. GMO’s Advantages
The advantages of GMO’s among human lives are clearly seen in two aspects that are food and health (medicine).9 . Genetically Modified (GM) plants are used as crops that are consumed by humans and animals. Theses crops are eventually produced faster through a genetic engineered process rather than a conventional one. The processed crops contains characteristic that can adapt and have high tolerance to drought, pests, and herbicide. As in for medication, GMOs are usually or expected to be used in

1) Insulin. As a form of medication for diabetes patients, insulin is one of the first GMO health products. In the making of insulin, a certain bacteria are modified genetically to adjust human’s insulin gene.10
2) GMO can produce medication such as growth hormone.11
3) GMO is now a lot used for Hepatitis B Vaccine (produced from yeast). In the future, it is expected that vaccines are inserted into plants or crops, so it is possible to eat the vaccines instead of injecting them.12

b. GMO Positive Impacts
GMOs advantages best seen in agriculture are divided into pests’ resistance and herbicide resistance.13 Bacillus thuringiensis or Bt, is a genetically engineered modification discussed widely for pests’ resistance. Bt is an organic insecticide used in the last decades as eradicator by organic farmers and a licensed method in controlling pests. The poison from Bt are isolated and inserted into crops’ gene, now elaborated in corns. The benefits of Bt are focusing on enhancing pests’

resistance. Despite all the positive impacts, critics have been given due to this issue for causing the high rates of monarch butterflies’ larvae.

c. GMO Negative Impacts

Although GMOs are proven to have a lot of positive returns to human lives, states’ concerns are never eased. In fact there a few of negative impact classified from GMOs.

1) Human Health Risk

The concerns when it comes to health risk consist of allergies, poisoning, and antibiotic resistance. On 2005, the National Research Arm of the Australian Government (CSIRO) Scientists reported that they have genetically engineered peas to be pests’ resistance which caused an allergy that led to a lung failure to rats. Due to that minor testing, the long term project was abandoned. This fact has rises the doubt weather the same impact would occur with humans.

2) Habitat Change

GM supporters declared that GM Crops have indirectly contributed to forest conservation by allowing marginal land to be processed which prevents wood cutting in the forest that changes field soil position. The fact is, experience indicates that the process of GM crops have increased the change of soil usage.

3) Pollution and Foreign Species Invasion

Agricultural modern practices applied in herbicide, pesticide, and fertilizer has causes severe damages in a big part of environments throughout the world, especially water and soil besides that, GM crops have introduced cross breeding between crops or natural plants that grows in the area. The genetic current alone is not a risk and several times are a part of a plant’s development or evolution. But it is always to be kept in mind that these kind of evolution can possibly lead into an uncontrollable plant which end up to a risk of extinction due to the foreign species.

3. GMO and the Precautionary Principle

The arguments of GMOs and the risks they carry are in spotlight between scientists. Scientists believe that the GMO works under the precautionary

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principle, because the GMO risks have a system. Two aspects of the system include spreading and the impact towards health and ecosystem. Ecologically, regarding to intended maintenance of soil and plants, GMO has its habit to spread without control thus the unknown risks. Cross breeding of a plant type with GMOs prevents their freedom that directs to a very wide and irreversible system effect without knowing the flaws. Precautionary measures that relates with GMOs consists of two requirements; appropriate science and supporting evidence as a part of valuing risks that has a role of introducing consequences from the GMOs. Whenever science is proven unqualified, then precautionary approach takes actions. From a practical implementation, the Cartegana Protocol on Biosafety (CPB) focuses on the precautionary aim. It states:

“Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects.”

C. Precautionary Principle: GMO’s Link Between Research and Trade
The different premise of GMOs between CPB and SPS Agreement has always been a problem world wide. Both of them do underline GMO in the export-import activities, yet CPB treats GMO as a research matter; an environmental reason, while SPS Agreement takes GMOs and commercialize them as a part of the international trade. Society feels that SPS Agreement opposite perspective of GMO from the CPB could lead to very dangerous causes. They need one thing in common to act as a “bridge” between them. The answer is one: precautionary principle. The WTO states that SPS Agreement will prioritize international trade without neglecting the environment through risk assessments and risk managements performed by each country domestically. To understand how to vision precautionary principle as the link between research and trade, it is likely to learn of GMO regulations in CPB and SPS Agreement.

1. GMOs in the Cartegana Protocol on Biosafety (CPB)
The Cartegana Protocol on Biosafety (CPB) was entered into force on 11 September 2003, and it is the first international law that regulates genetic engineering specifically. The existence of this rule reflects the global concerns towards the safety, health, and environment risks. For the first time on the international law history, there is an implicit acknowledgement that

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23 Article 11 point 8 of the Cartegana Protocol: Procedures for Living Modified Organisms Intended for Direct Use as Food or Feed or for Processing.
inherited GMOs from different organisms can carry a different risk and biological hazard as well. As of that statement, the international community considered a regulation to this matter is very much needed. The CPB states that GMOs do have high chance of giving impacts to the biodiversity, human health, and social economy, where the impact mentioned has to experience risk assessments or policy calculations.

Precaution is the base of this protocol, which takes the form of a policy making or risk assessment. CPB refers to “GMO” with the term of “LMO” or Living Modified Organisms, and it regulates the nature, transit, handling, and benefits of an LMO which could lead to minor issues when dealing with cultivation or sustainable biodiversity that is very risky to human health. CPB divides LMO into two types of procedures; direct contacts with environment, such as seed for soil cultivation or animal breeding and in forms of food, such as crops. CPB underlines the clear information given during import-export of a GMO. There are a few rules and procedures that regulate information during and export-import activity:

1) **The Biosafety Clearing House (BCH)**
   The BCH is the base of biological safety in the form of an internet forum. The BCH consist of information of national law, regulation, and guidance in applying CPB as adding information of countries’ reports that agree to import a GMO product.

2) **Advanced Informed Agreement (AIA)**
   AIA only regulates objects of living organisms such as seed or a fish to grow in a new environment and breed to create a new natured of GMO generation. Parties that export GMOs will give administrations to the receiving country. The country will either accept or reject based on the rules regulated by the AIA.

3) **Simpler System of Agricultural Commodity**
   GMOs that are in form of food (crops) are regulated in a simpler version. States that agree to import GM Foods are likely to report in the BCH. The purpose of reporting is to maintain the international trading system transparency.

2. **GMOs in the Sanitary and Phytosanitary (SPS) Agreement**
   On the 1st January 1995, the Sanitary and Phytosanitary (SPS) Agreement is established on the same time as the World Trade Organization (WTO). Originally, agreements that are relevant to GMO or particularly Genetically

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25 *Article 4 of Cartegana Protocol.*
26 *Article 7(1) of Cartegana Protocol.*
27 *Article 7(2) of Cartegana Protocol.*
28 See [http://bch.biodiv.org](http://bch.biodiv.org)
Modified Food (Labeling) are *The Agreement on Technical Barriers to Trade* (TBT Agreement) which regulates standards of production, process, packing, labeling and *The Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS Agreement) that regulates measurements needed to protect the lives and health of humans, plants, and animals. TBT Agreement is a continuous action of SPS Agreement. When it comes to giving standards, the SPS Agreement is known for the “three sister organizations” which are:

a. **Codex Alimentarius**
   Standardization for food product or agriculture in the form of texts with relates to practice, labeling, additions, inspection, certification, nutrition, and pesticide.

b. **International Plant Protection Convention (IPPC)**
   This convention regulates phytosanitary protection and management that as a reference by nations to prevent contamination of plant illness towards environment.

c. **World Organization for Animal Health (OIE)**
   OIE’s roles is to provide recommendations based on scientific proof to measure prevention, management, and demolishing animal diseases including zoo noses, especially in an occasion where humans, animals, and environment interacts.

D. **Benefits of the GMO between Sates**

1. **Indonesia**
   Indonesia does not take advantage of GMO commercially, but is on their way. PT Perkebunan Nusantara is recently given permission by Indonesia’s Ministry of Agriculture to introduce their products (GM Sugar) commercially. Indonesia does not have any exporting activities regarding to GMO. Although for import, Indonesia accepts tempeh, tofu, cotton, corn, and soybeans. Tempeh and tofu are a major part of food consumed in Indonesia. The main ingredients of both foods are soybeans. The rate of consume from soy beans is 2.7 million metric tons (MMT) which overcome 9% of Indonesia market. While soybean import are 4.3 MMT on 2014. As the 9th biggest cotton exporter in the world, Indonesia consumed 457 MMT, and corn takes place of consuming for 7.4 MMT. There are numerous of regulations that relate to GMO in Indonesia’s national law:
   a. Law No. 32 Year 2009 on Environment Protection and Management.
   b. Law No. 18 Year 2012 on Food.
   c. Ministry of Agriculture Decree No. 856 Year 1997.
   d. Government Regulation No. 28 Year 2004 on Food Safety, Quality, and Nutrition.

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Government Regulation No. 21 year 2005 on Biological Diversity.

Indonesia has ratified both CPB and the World Trade Organization (SPS Agreement) through Law No. 21 Year 2004 and Law No. 7 Year 1994.

2. Korea
Korea’s subjects for food labeling are soy bean, corn, cotton, sugar beer, alfalfa, and food products that are contained in crops. The labeling requirements are adopted both for domestic or imported products. There are two laws that regulate GMO:

3. Brazil
On November 1st, 2016, there are 58 genetically engineered products that are agreed to be cultivated commercially by Brazil; 34 products for corn, 10 products for soy bean, one product for eatable dried beans, and one product of a eucalyptus. The total area used to plant genetically engineered crops on previous years (2015/2016) reached 43 million hectares, which encourage Brazil to be the second most produced genetically engineered crops in the world. Those products with herbicide resistance outgrew the adoption by societies than can be seen by planting coverage of 65% for farm area, 19% for insect resistance, and 16% for gene stacking.  

Brazil has ratified the CPB on November 2003. The national law framework of Brazil for agricultural biotechnology is in the Law #11,460 of 2007 and Decree #, 591 of 2006. There are two government bodies that regulate biotechnology in Brazil:
   a. The National Biosafety Council or CNBS. This council act below the president and is responsible to establish National Biosafety Policy
   b. The National Technical Commission of Biosafety or CTNBio is established on 1995 under the first law of biosafety in Brazil (Law # 8,974).

4. German
In Germany, there are no products of GMO that are produced commercially; including GM seeds which are not allowed to sell overseas. Although so, seed companies like Bayer Crop Science, BASF, KWS from Germany, provides biotechnology seeds for farmers across the world. Germany used to

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cultivate MON 810 Corn from Monsanto until April 2009, because it was banned by the ministry of food, agriculture, and consumers protection, Ilse Aigner. Regarding to GMO regulations, on November 2003, German ratified the CPB. Domestically, the Federal Office of Consumer Protection and Food Safety or German abbreviation BVL is an authority in Germany that regulates GM Crops. The BVL is a part of the Federal Ministry of Food and Agriculture (BMEL). It accepts report from genetically modified provision requests and then hands over the report to the European Food Safety Authority (EFSA) which checks the quality of the data in order to evaluate risk potentials.

E. How do States Implement the Precautionary Principle?

1. Indonesia

The focus of precaution as an environmental law principle is when the cases of electric cable radiation and land slide. There are three environmental principle acknowledged in Indonesia, that is polluter pay principle, prevention principle, and precautionary principle. Law No. 32 Year 2009 on Environment Protection and Management (UUPPLH) regulates about precautionary principle on Article 2f. UUPLH also regulates an analysis of environmental impact that has to be fulfilled with every company or factor. The UUPLH article 47(1) and (2) stated:

(1) Every business and/or activity that has a potential of effecting the environment, threatening the ecosystem and lives, and/or human safety and health, are demand to organize and analysis of environmental risk.

(2) Environmental risk analysis mentioned in point (1) consists of:
   a. Risk assessment;
   b. Risk management; and/or
   c. Risk communication.

The precautionary principle can also bee seen in the Government Regulations No. 27 Year 2012 on environment permission and Government Regulations No. 5 Year 2012 on types of business that obligates to analyze environment impact. The Ministry of Agriculture Regulation No. 61/Permentan/Ot.140/10/ on testing, evaluating, releasing, and withdrawing varieties of GM foods was created as a preventing action upon GM foods. Unfortunately, in this regulation there are no indication of precautionary principle, environment risk

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41 Pasal 3 ayat (1) dan (2) PP No. 27 Tahun 2012 tentang Izin Lingkungan.
analysis, and environment permission. This is not relevant with the higher regulations such as CPB, UUPPLH, Government Regulations No. 27 Year 2012, and Government Regulations No. 5 Year 2012 and need a re-evaluation based on the principle of *lex superior derogate lege inferiori*.\(^\text{42}\)

2. **Korea**

There are three environment regulations in Korea, but none of them have implemented the precautionary principle.

- **Framework Act on Environmental Policy (FAEP)1990** and **Natural Environment Conservation Act (NECA)1991** only introduce the prevention principle instead of precautionary principle, both of them does not mention lack of science and focus on the economic sides.\(^\text{43}\)

- **Act on Impact Assessments on Environment, Transportation, Disasters (AIA) 1999** did not mention of the precautionary principle but rather an unclear version of sustainable development.\(^\text{44}\)

3. **Brazil**

Precautionary principle is one of the environmental aspects that are very much deliberated. In Brazil, the implementation of this principle was taken seriously since the “RR Soy Bean” Case occurred. The case involved *Instituto Brasileiro de Defesa do Consumidor (ICED)* that sues the National Technical Commission on Biosafety (CTNBio).\(^\text{45}\)

ICED did not agree for the reaction CTNBio gave in provisioning the soy bean from Monsato without a proper standardization of precautionary approach. Brazil Court of District underlined that CTNBio should have taken *estudo de impacto ambiental* EIA seriously. EIA is a study to decide for a GM qualifications. On the other side, Brazil High Court was satisfied enough with CTNBio’s administration as a form of precaution it self. Through this case, the government finally changed the authorities of provisioning a GMO. On November 2003, Brazil’s President has established a biosafety law that demand CTNBio to take precautionary principle in giving provisions seriously.\(^\text{46}\)

4. **German**

*The Vorsorgeprinzip* Has a big role in making environmental law policies in Germany. Sometimes, the principle is the main reference in the national policies. Besides that *The Vorsorgeprinzip* has become a link between other principles. Cameron and Abouchar stated that


\(^{43}\) See Article 7-2 of FAEP and Article 3(5) NECA.

\(^{44}\) See Article 1 of AIA


*Verschelechterungsverbot* and correction at source is another special form of the *vorsorgeprinzip*.

Water management in German has included *vorsorgeprinsip* in a wide substance. But, for a few decades the principle is never adopted in energy resources management. Matter of fact, the environmental principle never taken places in the energy resources policies through the federal Energy Management Act/Energiewirtschaftsgesetz (EnWG), because of that, the energy resource policies are in deliberation of destruction, while precautionary principle can be seen in Article 2 (4) of EnWg. The Article declares the probability in minimizing environmental damage risks.

### Table 1.1

<table>
<thead>
<tr>
<th>No.</th>
<th>Country</th>
<th>Benefit of GMO</th>
<th><em>Cartegana Protocol</em></th>
<th><em>SPS Agreement</em></th>
<th>Precautionary Principle</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Indonesia</td>
<td>Accepted as food</td>
<td>Ratified through Law No. 21 Year 2004</td>
<td>Ratified through Law No. 7 Year 1994</td>
<td>Law No. 32 Year 2009, Government, Regulations No. 27 Year 2012, Government Regulation No. 5 Year 2012.</td>
</tr>
<tr>
<td>2.</td>
<td>Korea</td>
<td>Accepted as food</td>
<td>-</td>
<td>Ratified on 1 January 1995</td>
<td>Adapting</td>
</tr>
<tr>
<td>3.</td>
<td>Brazil</td>
<td>Accepted as food and feed</td>
<td>Ratified on November 2003</td>
<td>Ratified on 1 January 1995</td>
<td>CTNBio/EIA</td>
</tr>
<tr>
<td>4.</td>
<td>Germany</td>
<td>prohibit GMO</td>
<td>Ratified on November 2003.</td>
<td>Ratified on 1 January 1995</td>
<td><em>The Vorsorgeprinzip</em></td>
</tr>
</tbody>
</table>

From the table above, we can see that Indonesia, Korea, and Brazil support GMOs, but Germany does not. From four countries, only one does not embrace the precautionary principle, which is Korea. The precautionary absence does not mean GMOs can be banned. While precautionary existence does not mean GMOs are welcomed.

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F. Conclusion

The GMO is regulated specifically by the Cartegana Protocol on Biosafety (CPB). The CPB underlines that due to research issue, GMO’s are exported and imported by looking up to certain regulations such as Biosafety Clearing House, Advanced Informed Agreement, and simpler system agricultural commodity. Because of these high standards, it became a problem when GMO is commercialized through the Sanitary and Phtyosanitary (SPS) Agreement with presumption of minor qualifications. Precautionary principle came through between these regulations that takes both CPB and SPS Agreement on the same page. This is proven by SPS Agreement which acts through risk assessment and management. The SPS Agreement also has international standard organs which are Codex Alimentarius (food), International Plant Protection Convention, World Organization of Animal Health.

Every country has its own ideas on GMOs; Indonesia, Korea, and Brazil support the GMOs, while Germany prohibited the GMOs. As for implementing the precautionary principle, nations implement by adopting through their national law; Indonesia (environment management act, government regulations No. 27 year 2012, and government regulations No. 5 year 2012), Korea (still adapting), Brazil (CTNBio and estudo de impacto ambiental), and Germany (The Vorsorgeprinzip). Out of four countries, only one does not embrace the precautionary principle, which is Korea. The precautionary absence does not mean GMOs can be banned. While precautionary existence does not mean GMOs are welcomed. This means that the precautionary principle is not permission or requirement for GMO to be acknowledged in countries, that precautionary principle are an effort to minimize risk whenever it is “intended” not “automatically”.

References


Cartegana Protocol on Biosafety
The Sanitary and Phytosanitary Agreement


FAO; 2003,” Genetically Modified Organisms and Aquaculture”. FAO Fisheries Circular, No. 989, pg. 4, accessed from https://doi.org/10.1108/00346659410048901


See http://bch.biodiv.org