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### A Comparative Study of GMO Labeling and Liability Systems in the US, EU, and South Korea: The Circumstances and a Future Potential for Harmonization

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**A COMPARATIVE STUDY OF GMO LABELING AND  
LIABILITY SYSTEMS IN THE US, EU, AND SOUTH KOREA:  
THE CIRCUMSTANCES AND A FUTURE POTENTIAL FOR HARMONIZATION**

**MOONSOOK PARK**

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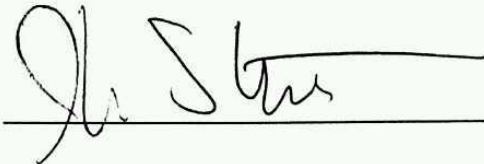
MoonSook Park

Submitted to the faculty of Indiana University Maurer School of Law  
in partial fulfillment of the requirements  
for the degree  
Master of Laws – Thesis

April 2014

Accepted by the faculty, Indiana University Maurer School of Law, in partial fulfillment of  
the requirements for the degree of Master of Laws – Thesis.

Thesis Committee



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Date of thesis submission

April 2, 2014

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## **ABSTRACT**

With the remarkable development of GMOs, GMO trade has also increased. The different attitudes on GMOs among the countries all over the world, specifically the US, EU, and South Korea, have the potential to create international trade conflicts. In order to mediate the conflicts, reasonable labeling and liability systems need to be established to prevent potential GMO risks. The Biosafety Protocol regarding the transboundary movement of GMOs exists to resolve such tensions, but it fails to sufficiently solve the problems and provide clear regulations concerning GMO labeling and liability systems.

A successful GMO labeling and liability system should emphasize the precautionary principle and use a cooperative approach that considers all views on GMOs. After reviewing current international and domestic standards, particularly the ones in South Korea, the GMO labeling system should be mandatory, supporting the “consumer’s right to know.” Additionally, the new GMO liability system should reflect a civil liability system, where standards protect the party injured by GMOs in the direction of compensating the damage fully and efficiently by using the precautionary principle.

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## I . Introduction

Genetically Modified Organisms (GMOs) are organisms where the genetic materials have been altered and newly produced in a way that does not occur naturally. There are many different terminologies for GMOs all over the world, such as Living Modified Organisms (LMOs), Genetically Engineered Organisms, and Biotechnology Products. As seen in the terminology used, each country regards them differently.<sup>1</sup> For clarification, this paper will use the term GMOs, except in the case where the law has an official title, such as the *LMO Act* of South Korea.<sup>2</sup> The term GMO was chosen because it is regarded as the most universal and comprehensive term.

Before the discussion on GMO regulation, a brief explanation on the history and present conditions about GMO development and trade will be useful for better understanding. GMOs fall under the field of biotechnology, which deals with technological applications to make or modify products for specific use. The growth of biotechnology has developed the production of GMOs. GMOs initially started in the US, and the first approval of a product was the delayed ripening tomato by the Calgene Company in 1994.<sup>3</sup> Globally, the cultivation

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<sup>1</sup> The term LMO focuses on the meaning of “living” organisms that can self-reproduce and the representative international norm used to regard GMOs (e.g., the “Cartagena Protocol on Biosafety to the Convention on Biological Diversity” [hereinafter the *Biosafety Protocol*]) uses the term of LMOs. The US prefers to use the term Genetically Engineered Organisms or Biotechnology Products, and the EU prefers to use the term GMOs.

<sup>2</sup> In South Korea, there is the “Act on Transboundary Movements of Living Modified Organisms” as a domestic implementation legislation of the *Biosafety Protocol*. It is called the *LMO Act*. The Korea Biosafety Clearing House provides the English draft version of the *LMO Act*. See *Laws and Regulations*, KOREA BIOSAFETY CLEARING HOUSE, <http://www.biosafety.or.kr/english/laws/The%20Act%20on%20Trans-boundary%20Movements%20of%20Living%20Modified%20Organisms.pdf>

<sup>3</sup> CLIVE JAMES & ANATOLE F. KRATTIGER, INT’L SERV. FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATIONS (ISAAA) BRIEF NO. 1, GLOBAL REVIEW OF THE FIELD TESTING AND COMMERCIALIZATION OF TRANSGENIC PLANTS, 1986 TO 1995: THE FIRST DECADE OF CROP BIOTECHNOLOGY 23 (1996), available at <http://www.isaaa.org/resources/publications/briefs/01/download/isaaa-brief-01-1996.pdf>

area of GMOs was 1.7 million hectares<sup>4</sup> in 1996 and it increased to 170 million hectares in 2012. The fact that it took just 16 years to reach a 100-fold increase shows that Genetically Modified crops (GM crops) has been the fastest adopted biotechnology in recent history.<sup>5</sup> The US continues to be the leading country for using GM crops with 69.5 million hectares and 90 percent of its crops being GM products, including corn, soybeans, cottons, sugar beets and canola.<sup>6</sup>

With the development of GMOs, GMO trade has also increased. The US is the most representative country to export GMOs. Brazil, Argentina and Canada are other major GMO exporting countries. The EU and South Korea are countries that import GMOs. The EU has a high degree of self-sufficiency for food, but the EU is one of the importing countries in a trade relationship with the US. In contrast, South Korea is importing a considerable amount of GMOs from other countries. In 2012, South Korea imported 7.84 million tons of GMOs from the US, which is equivalent to 2.67 billion dollars.<sup>7</sup> The countries from which South Korea imports GMOs vary from the US to Brazil, to Argentina, and many more. However, the US is still the top country to export GMOs to South Korea.<sup>8</sup> Both developed countries and developing countries are participating in GMO development and GMO trade, and it is

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<sup>4</sup> The hectare is a unit area used for measuring land. 1 hectare is defined as 10,000 square meters or about 2.471 acres.

<sup>5</sup> CLIVE JAMES, INT'L SERV. FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATIONS (ISAAA) BRIEF NO. 44, GLOBAL STATUS OF COMMERCIALIZED BIOTECH/GM CROPS: 2012 1-4 (2012), *available at* <http://www.isaaa.org/resources/publications/briefs/44/download/isaaa-brief-44-2012.pdf>

<sup>6</sup> *See Id.*

<sup>7</sup> JeoungSook Cho, *GMOs going through at a glance with major statistics data of 2012*, 14-1 BAIOSEIPEUTI JEONEOL [BIOSAFETY JOURNAL] 21 (2013). Biosafety Journal is one of the two main publications issued by the Korean Biosafety Clearing House ("KBCH"). The Biosafety Journal has been issued quarterly since 2000. It includes a variety of articles by scholars and government officers, focusing on the issues related to R&D and the safety of GMOs. On the other hand, the Biosafety White Paper has been issued yearly since 2003. It mainly contains the ministries' circumstances in implementing the *LMO Act*. *See Publications*, KOREAN BIOSAFETY CLEARING HOUSE, <http://www.biosafety.or.kr/english/index.asp>

<sup>8</sup> *See Id.*

predicted that GMO development and trade will continue to grow. This continued development and trade of GMOs will ultimately lead to many conflicts and disputes between countries based on each country's own interests. Therefore, reasonable and persuasive GMO regulation is needed on the international level.

The *Biosafety Protocol* was one agreement regarding GMOs on an international level, focusing on the transboundary movement of GMOs. However, the *Biosafety Protocol* conflicts with the existing international trade treaty: the World Trade Organization (WTO). The WTO rules aim to guarantee "free trade" between countries. However, the *Biosafety Protocol* emphasizes the protection of the environment from the risks of GMOs under the precautionary principle. Besides the conflicts with the WTO rules, the *Biosafety Protocol* itself is problematic in that it is not sufficient and needs clarification of two important parts of GMO regulation – GMO labeling and liability.

Another existing problem with GMO regulation lies in the different domestic attitudes within the current domestic laws. These laws are based on preventative and favorable policies for GMOs, where only one side of GMOs is emphasized. Proponents of GMOs highlight the benefits of GMO and argue that GMOs could be an alternative for the growing world population and that it could be helpful for the human health and the environment. On the other hand, opponents of GMOs stress the risk of GMOs and say that there exists a threat of disrupting the ecosystem. This threat could potentially harm the environment and human health, possibly creating new viruses or allergenic problems. However, there is no accurate and obvious scientific evidence to show the risk or safety of GMOs. This principle is called "scientific uncertainty."<sup>9</sup> Therefore, this scientific uncertainty

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<sup>9</sup> Among scientists, there exists a debate on the experimental result and methodology of GMO risks. Also, environmentalists change their opinion often about GMO risks. This situation increases confusion on the

creates dissonance between the domestic GMO regulations in nations around the world, particularly the US, the EU and South Korea.

This thesis is comprised of five sections. Section II looks into the philosophical perspectives regarding GMOs, which will be the basis of GMO regulations, and explores how international laws and domestic laws in the US, the EU, and South Korea reflect these perspectives.

Section III seeks to find an effective GMO labeling system to protect the consumers' right to know and analyzes the consistency of the future ideal labeling system with the existing WTO rules. Currently, the GMO labeling system in the EU enforces the strongest mandatory labeling system with the traceability system, and the US enforces a voluntary one. For setting up reasonable international standards and harmonizing different attitudes among the US, the EU, and South Korea, South Korea's attitudes has the possibility of being a model for concession. However, South Korea's regulation is not fully recommendable due to its ineffective GMO labeling systems, resulting from many exception clauses. South Korea enforces a mandatory liability system, but also establishes certain conditions for mandatory labeling. Due to these exception clauses, considering the presence of GM materials in final products and the priority of GM crops used in GM foods, it is rare to actually find GMO labeling in South Korea.<sup>10</sup> If South Korea's labeling system is well revised to close the loopholes, it could be a potential model in creating a GMO labeling system between pro-GMO and anti-GMO countries.

Many loopholes also exist in the GMO liability and redress system, listed in Section

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GMOs. See, e.g., Aaron Perlut, *Mark Lycas: From GMO Hater to Supporter*, FORBES, July 9, 2013, available at <http://www.forbes.com/sites/aaronperlut/2013/07/09/mark-lynas-from-gmo-hater-to-supporter/>

<sup>10</sup> See SungYong Park & SukChul Kim, *A Study on the Trade Policy and Issues of GMO labeling*, 37-1 MUYEOKHAKHOEJI [Trade Law Journal] 108 (2012).

IV. In order to fix the current *Liability and Redress Supplementary Protocol*<sup>11</sup>, it is important to find the loopholes and set up an international agreement for an effective and sufficient relief of damages caused by the transboundary movement of GMOs. This GMO liability regime must also reflect GMO characteristics under the *Biosafety Protocol*.<sup>12</sup> With the effort on international level, all three countries (the US, the EU, and South Korea) are needed to establish a new and reasonable domestic liability regime.

In order to achieve an international regulation system, it is imperative that a cooperative approach by all participating countries is taken in solving and negotiating the GMO regulation problems. This will ensure to mitigate the current gaps between the countries and successfully create an international standard for GMO regulation. Therefore, this paper will use a legal analysis on current international and domestic laws and situations, in combination with major principles within the field, to come up with a resolution.

## II. Philosophies and laws about GMO regulations

Many countries vary on their attitudes about GMOs. As the trade of GMOs is increasing, this difference causes international conflict. The difficulty of solving GMO problems is due to the different interpretations and participation of international norms, and the different domestic laws. Each country's conflicting laws and policies are based on the

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<sup>11</sup> The official name of this supplementary protocol is "Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety" [hereinafter the *Liability and Redress Supplementary Protocol*].

<sup>12</sup> KAREEN L. HOLTBY, WILLIAM A. KERR & JILL E. HOBBS, INTERNATIONAL ENVIRONMENTAL LIABILITY AND BARRIERS TO TRADE: MARKET ACCESS AND BIODIVERSITY IN THE BIOSAFETY PROTOCOL 142 (2007).

country's own philosophy about GMOs.<sup>13</sup> Therefore, to see exactly where each country stands, it is necessary to take a look at the GMO regulation philosophies of each nation before looking at the varying domestic laws.

### **A. Background for GMO regulation**

The US, EU, and South Korea all have different attitudes about GMOs when looking at both legal and administrative perspectives. A big gap between the two main developed countries, the US and EU, is especially evident. This different approach depends on how the countries prioritize biotechnological development values and protecting human and environmental safety. The US emphasizes the positive aspects of developing biotechnology and the international trade rulings, which focuses on free trade (the concerns about the export and transport of goods between different countries).<sup>14</sup> On the other hand, the EU emphasizes the risk of GMO development and the need for regulations according to the international environmental law, focusing on health and environmental protection.<sup>15</sup>

This kind of tension on legal interests is found in the fields of international law. The international trade laws and the international environmental laws have distinct legislative intent, which inevitably leads to conflicts between the international norms and trickles down

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<sup>13</sup> GMO related issues could be analyzed from a variety of perspectives, such as science, risk, politics, society, and culture. See David Winickoff, Sheila Jasanoff, Lawrence Busch, Robin Grove-white & Brian Wynne, *Adjudicating the GM food Wars: Science, Risk, and Democracy in World Trade Law*, 30 YALE J. INT'L L. 81, 93-99 (2005).

<sup>14</sup> See SIMONETTA ZARRILLI, POL'Y ISSUES IN INT'L TRADE AND COMMODITIES STUD. SERIES NO. 29, INTERNATIONAL TRADE IN GMOs AND GM PRODUCTS: NATIONAL AND MULTILATERAL LEGAL FRAMEWORKS 7 (2005).

<sup>15</sup> See *Id.*



to domestic laws and policies.<sup>16</sup> For example, if the GMO import country emphasizes health and environmental laws, then the country is likely to assert many exceptions to international trade laws as well. Therefore, the GMO export country will feel as if the trade laws have been violated, ultimately leading to conflict between the two countries with different ideals.

Each country also has its own interests and intents about GMOs regarding the economy and politics. The US is the largest GMO exporting country in the world when discussing economic power.<sup>17</sup> Recently, a study has shown that political power has an effect on the GMO regulations of countries between developed and developing countries.<sup>18</sup> The developing countries' GMO policy could be influenced by other developed countries, such as the US and EU. Finally, the cultural difference could lead to diverse approaches on GMOs.<sup>19</sup> For example, Europeans have food practices that prefer natural foods, stressing the quality of foods, while the US tends to practice food technologies, applying new technologies to develop food in order to increase quantity.<sup>20</sup> However, by understanding each country's opinions on GMOs, this will allow for an agreeable solution in regulating GMOs.

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<sup>16</sup> See *Id.* at 24.

<sup>17</sup> Large companies in the US, such as Monsanto, Nestle, General Mills, and PepsiCo, experience cost benefits by using the added ingredients of corn, rice, canola oil and soybeans, which were the first FDA-approved GMOs. See Rachel Hennessey, *GMO Food Debate In the National Spotlight*, FORBES, Nov. 3, 2012, <http://www.forbes.com/sites/rachelhennessy/2012/11/03/gmo-food-debate-in-the-national-spotlight/>

<sup>18</sup> See Alison Peck, *The New Imperialism: Toward an Advocacy Strategy For GMO Accountability*, 21 GEO. INT'L ENVTL. L. REV. 37, 60 (2008) (explaining a right of self-determination as a basis of this theory and states that the US pro-GMO policy has a risk of violating other countries' right of self-determination).

<sup>19</sup> See Cara V. Coburn, *Out of the Perti Dish and Back to the People: A Cultural Approach to GMO Policy*, 23 WIS. INT'L L.J. 283, 294 (2005).

<sup>20</sup> *Id.*; Tassos Haniotis, *The Economics of Agricultural Biotechnology: Differences and Similarities in the US and the EU*, in GENETICALLY MODIFIED ORGANISMS IN AGRICULTURE –ECONOMICS AND POLITICS 173 (Gerald C. Nelson ed., 2001).

## **B. General philosophies for GMO regulation**

Looking broadly at the theories approaching GMOs, there are two different approaches on GMO regulations. One is the approach that concerns the possible risk of GMOs and the other is concerned with favoring GMOs. This section will examine some of the principles under these different perspectives in order to learn where each country's GMO regulation is based on and to find a reasonable approach. It will also examine the emphasis on the coexistence of GMOs and non-GMOs, which first began in the EU to find an agreeable approach for all countries.

### **1. Preventative measures for GMO regulation**

#### **a. Use of risk assessment**

The policies and regulations on GMOs could vary according to how each country evaluates the risk of GMOs. Each country takes an action based on measured effects by risk assessment. The EU Directive provides an environmental risk assessment and authorization procedure of GMOs.<sup>21</sup> The risk assessment is obligated to consider the “risks to human health and the environment, whether direct or indirect, immediate or delayed, where the deliberate release or the placing on the market of GMOs may pose” under the Directive.<sup>22</sup> The domestic legislation of South Korea also uses the risk assessment of GMOs under the *LMO Act*, a comprehensive and general law about GMOs. Meanwhile, the US utilizes the risk

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<sup>21</sup> See Ruth MacKenzie & Silvia Francescon, *The Regulation of Genetically Modified Foods in the European Union: An Overview*, 8 N.Y.U. ENVTL. L. J. 530, 530 (2000).

<sup>22</sup> See Margaret Rosso Grossman, *The Coexistence of GM and Other Crops in the European Union*, 16-SPG KAN. J. L. & PUB. POL'Y 324, 336 (2007).

assessment for GMOs by using existing laws that deal with potentially hazardous products.<sup>23</sup>

Presently, the risk assessment is used in regards to regulating GMOs. The *Biosafety Protocol*, the current representative international norm about GMOs, has two articles of risk assessment and risk management in Article 15 and 16. Furthermore, the Annex III of the *Biosafety Protocol* provides the specific contents of risk assessment.<sup>24</sup> In addition, the Agreement on Sanitary and Phytosanitary (SPS Agreement), one of the existing international trade laws under the WTO, provides that the measures to protect human or environment should be based on a risk assessment in the Article 5.1.<sup>25</sup> The risk assessment is the first and essential part of GMO regulation and is provided in both international and domestic norms. However, each country's standards and results of the GMO risk assessment are shown differently.

b. Precautionary principle

The precautionary principle is relevant to risk assessment in that the proved scientific data and evaluation of them is necessary when the regulation on GMOs was taken under the precautionary principle.<sup>26</sup> In the spectrum of the amount of information with time, the

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<sup>23</sup> The assessment of GMOs within the US was first carried out by the FDA in 1992. The result of the assessment in the US stated that new GMO products were considered to be genetically recognized as safe ("GRAS"). See Alison Peck, *Leveling the Playing Field in GMO Risk Assessment: Importers, Exporters and the Limits of Science*, 28 B.U. INT'L L.J. 241, 246 (2010).

<sup>24</sup> See RUTH MACKENZIE ET AL., AN EXPLANATORY GUIDE TO THE CARTAGENA PROTOCOL ON BIOSAFETY 105 (2003).

<sup>25</sup> With regard to the GMO risk assessment, there is an opinion that emphasizes public participation under the SPS Agreement. See Winickoff et al., *supra* note 13, at 99-102 (stating that public input could play an important role in GMO risk assessment under the scientific uncertainty regarding GMOs).

<sup>26</sup> See John S. Applegate, *The Taming of the Precautionary Principle*, 27 WM. & MARY ENVTL. L. & POL'Y REV. 13, 26 (2002) (explaining that the European Commission repeatedly emphasized the need for risk assessment based on available information and states "before the precautionary principle is invoked, the scientific data relevant to the risks must first be evaluated."). See also, Anne Ingeborg Myhr, *The Role of Precautionary Motivated Science in Addressing Scientific Uncertainties Related to GMOs*, in BIOSAFETY FIRST - HOLISTIC APPROACHES TO RISK AND UNCERTAINTY IN GENETIC ENGINEERING AND GENETICALLY MODIFIED

precautionary principle plays an important role to permit regulations, despite the lack of accumulated and completely scientific information.<sup>27</sup>

It is necessary to review the precautionary principle when discussing GMOs. The GMO labeling system and GMO liability system are understood as policies based on the precautionary principle. The precautionary principle is a fundamental concept in international environmental law and policy.<sup>28</sup> The emphasis on precautionary principle will be helpful to set up a strict GMO regulation by preparing for and preventing GMO risks in both GMO labeling and liability systems. The precautionary principle, one of the *Rio Declarations on Environment and Development* (Principle 15), has been adopted in many regional and global instruments.<sup>29</sup> This principle states that the significant risks of current and new technologies should be anticipated and prevented.<sup>30</sup> The anthropogenic harm to human health and the environment should be avoided or minimized under this principle. In addition, technological activities should be restricted when their environmental results are uncertain but potentially serious.<sup>31</sup>

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ORGANISMS 279 (Terje Traavik & Lim Li Ching eds., 2007) (stating that “implementing a precautionary approach might require a renewed look at the science underpinning risk assessment and management of GE and GMO release.”).

<sup>27</sup> See Applegate, *supra* note 26, at 75 (stating that “a precautionary principle that expressly permits regulation while a significant amount of uncertainty remains is, therefore, an important bulwark against endless demands for more information.”). See also Anne Ingeborg Myhr, *The Precautionary Principle in GMO Regulations*, in BIOSAFETY FIRST -HOLISTIC APPROACHES TO RISK AND UNCERTAINTY IN GENETIC ENGINEERING AND GENETICALLY MODIFIED ORGANISMS 458 (Terje Traavik & Lim Li Ching eds., 2007) (mentioning that “precautionary principle is a normative principle for making practical decisions under conditions of scientific uncertainty.”).

<sup>28</sup> See Applegate, *supra* note 26, at 13.

<sup>29</sup> The Principle 15 of the Rio Declaration was adopted at the UN Conference on Environment and Development in 1992. It provides that “in order to protect the environment, the precautionary approach shall be widely applied by States 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.” See MACKENZIE ET AL, *supra* note 24, at 12-13.

<sup>30</sup> See John S. Applegate, *The Prometheus Principle: Using the Precautionary Principle to Harmonize the Regulation of Genetically Modified Organisms*, 9 IND. J. GLOBAL LEGAL STUD. 207, 248 (2001).

<sup>31</sup> See Applegate, *supra* note 26, at 13. This precautionary principle has been tamed over time with a

Until now, there has been a debate on the interpretation of the precautionary principle and whether the precautionary principle is an international customary law. However, this principle plays a very important role in solving international environmental issues and has been reflected in many environmental treaties. The *Biosafety Protocol* also reflects the precautionary principle within some key provisions.<sup>32</sup> Meanwhile, even though the WTO related provisions generally limit GMO regulations, the SPS Agreement (part of the WTO agreement) includes a provision reflecting the precautionary principle in Article 5.7. The EU is one of the main countries that has adopted this precautionary principle and has reflected this principle in its GMO policies. The very strict GMO labeling system in Europe shows how the EU favors this principle.<sup>33</sup>

## **2. Approaches favorable to GMO production**

### **a. Substantial equivalence**

Substantial equivalence of GMOs states that GMOs and non-GMOs are substantially equivalent in biochemical composition. According to this substantial equivalency, if a non-GM product is generally considered safe, then the GM product is also generally considered to be safe.<sup>34</sup> Therefore the US has a GMO-friendly policy, which is explicitly different from the EU. The US GMO regulation is based on the doctrine that GM products should be regulated

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consistent pattern in international and national environmental policy; the variation could be expressed through trigger, timing, response and iteration. See Applegate, *supra* note 26, at 16.

<sup>32</sup> See MACKENZIE ET AL, *supra* note 24, at 13-14.

<sup>33</sup> See Applegate, *supra* note 30, at 247.

<sup>34</sup> See Dorothy Du, *Rethinking Risks: Should Socioeconomic and Ethical Considerations Be Incorporated into the Regulation of Genetically Modified Crops?*, 26 HARV. J.L. & TECH. 375, 377 (2012).

in the same way as its non-GM counterparts.<sup>35</sup> The FDA in the US has adopted the substantially equivalence concept and maintained this stance today. Under this substantial equivalence concept, GMO labeling is considered unnecessary, causing the US not to adopt a GMO labeling system.<sup>36</sup> Therefore, countries in favor of this approach are lenient to GMO development and easily accept GMOs, which also leads the countries to regulate GMOs passively with existing laws, and not newly proposed laws for GMO regulation.

b. Sufficient scientific evidence-based approach

The approach emphasizing the need for scientific evidence requires there to be a sufficient amount of scientific evidence to prove GMO risks for regulating GMOs. The US prefers this approach in order to be favorable towards using GMO products. This approach allows for technological developments and markets for these new technologies until scientific analysis proves that scientific risk is apparent.<sup>37</sup> Additionally, the WTO also approaches the GMO issues emphasizing scientific clear and significant evidence, and this approach is especially consistent with the WTO's SPS Agreement. As it states in Article 2.2 and 5, and also known from the panel's standard of review, the SPS measures should be based on scientific principles.<sup>38</sup> Because this approach essentially requires confirmed scientific evidence of harm caused by GMOs before the ban on GMOs, this approach is favorable to countries like the US under the scientific uncertainty principle. In other words, the requirement of demonstrated scientific evidence and testing results to prove GMO risks under this approach makes the US reluctant to GMO regulations and favorable to GMOs itself.

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<sup>35</sup> See PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY [PIFB], ISSUES IN THE REGULATION OF GENETICALLY ENGINEERED PLANTS AND ANIMALS 3 (2004) [hereinafter PIFB report].

<sup>36</sup> See Du, *supra* note 34, at 392.

<sup>37</sup> See Coborn, *supra* note 19, at 300.

<sup>38</sup> See Guy R. Kundsén, *Where's the Beef? How Science Informs GMO Regulation and Litigation*, 48 IDAHO L. REV. 225, 241 (2012).

### 3. Searching for a middle ground approaches

#### a. Reconciliation approach

As a country that has experienced a dramatic economic development, South Korea has played a role to mitigate developed countries and developing ones. Moreover, in an international society, South Korea is in a position that wants to maintain good interactions with the US and EU. South Korea's policy has changed from a negative attitude towards GMO regulation to a positive one.<sup>39</sup> South Korea's GMO regulations reflect this status of mitigating and coexisting with both countries to some extent.

As for the GMO labeling regulations, South Korea has the mandatory labeling system under the *LMO Act*, like the EU. However, when it comes to the specific implementation of the *LMO Act*, South Korea's regulation is not as strict as EU's implementation of the *Regulation 1829/2003* and *1830/2003* (the EU's two main Directives about GMO labeling system). Therefore, if placed on a spectrum, the GMO regulation policy of the South Korea could be placed between the US and EU regulation systems.

#### b. Coexistence approach

Recently, the concept of coexistence has been discussed as a new and flexible approach for GMO regulations in the EU.<sup>40</sup> The European Commission published guidelines

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<sup>39</sup> At the beginning stages of regulation, the government estimated that GM crops are safe and substantially equivalent to non-GM products (similar to the US approach). However, the government policy has shifted to needing GMO regulations after a long period of debates. See SeongEun Cho & SunHyuk Kim, *Institutions, Interests, and ideas as Determinants of Public Policy: A Comparative Analysis of GMO Labeling Policies in the EU, South Korea, and the US*, 44-3 SEOULDAEHAKGYO HAENGJEONGNONCHONG [Seoul National University Korean Journal of Policy Administration] 15-18 (2006).

<sup>40</sup> For details on the national implementation (e.g., France, Italy, Spain and UK) regarding coexistence in the EU, see Luc Bodiguel, Michael Cardwell, Ana Carretero Garcia & Domenico Vitti, *Coexistence of Genetically Modified, Conventional, and Organic Crops in the European Union: National*

in 2003 for enforcing a coexistence regulation.<sup>41</sup> This approach proposes for the coexistence of traditional crops with genetically modified crops in agricultural environment.<sup>42</sup> In other words, the coexistence policy refers to the farmer's ability to make choices between genetically modified, conventional, and organic products that are in compliance with current European labeling and traceability standards. This enables the moving route of the food to be followed as a stricter system than just labeling.<sup>43</sup> The adoption of this coexistence approach is helpful to avoid rapid technological substitutions of conventional crops by GM products and guarantee the survival of organic production.<sup>44</sup> In addition, it is also helpful to avoid economic losses caused by an adventitious mixture, meaning unintended influx of GM seeds due to natural causes.<sup>45</sup> Some measures preventing GM pollen from drifting into other conventional cultivation fields need to be taken under this coexistence approach.<sup>46</sup>

The coexistence approach enables consumers' right to be ensured in the EU's labeling system because the integrity of labeling could remain when the intermixing is kept as minimum as possible. Therefore, this approach has an importance in that it enhances the consumer's right to choose between GM products and non-GM products, as well as the farmer's right to choose.

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*Implementation*, in *THE REGULATION OF GENETICALLY MODIFIED ORGANISMS: COMPARATIVE APPROACHES* 166-195 (Luc Bodiguel & Michael Cardwell eds., 2010).

<sup>41</sup> *Freedom of Choice: Selecting The Deliberately Applied System*, GMO COMPASS, [http://www.gmo-compass.org/eng/regulation/coexistence/133.freedom\\_choice\\_selecting\\_deliberately\\_applied\\_system.html](http://www.gmo-compass.org/eng/regulation/coexistence/133.freedom_choice_selecting_deliberately_applied_system.html) (last visited Feb. 17, 2014).

<sup>42</sup> See Margaret Rosso Grossman, *Coexistence of Genetically Modified, Conventional, and Organic Crops in the European Union: The Community Framework*, in *THE REGULATION OF GENETICALLY MODIFIED ORGANISMS: COMPARATIVE APPROACHES* 123 (Luc Bodiguel & Michael Cardwell eds., 2010).

<sup>43</sup> See Grossman, *supra* note 22, at 325.

<sup>44</sup> See Justo Corti Varela, *The New Strategy on Coexistence in the 2010 European Commission Recommendation*, 1 EUR. J. RISK REG. 353 (2010).

<sup>45</sup> See Grossman, *supra* note 42, at 130.

<sup>46</sup> *Coexistence in Agriculture: Minimising Pollen Traffic*, GMO COMPASS, [http://www.gmo-compass.org/eng/regulation/coexistence/134.coexistence\\_agriculture\\_minimising\\_cross\\_pollination.html](http://www.gmo-compass.org/eng/regulation/coexistence/134.coexistence_agriculture_minimising_cross_pollination.html) (last visited Feb. 23, 2014).



#### 4. Summary

Looking at the GMO regulation policies broadly within the three countries, it could be stated that the US has a favorable to GMO (Pro-GMO) policy based on the substantially equivalent principle. On the other hand, the EU is in favor of GMO regulations based on the precautionary principle and the coexistence between GMOs and non-GMOs. South Korea's policy is currently experiencing changes in its GMO policies. However, it is noteworthy to recognize that there are critiques on both the radically different US and EU regulations. There are many in support of considering non-scientific issues surrounding GMOs in the US.<sup>47</sup> Likewise, there is an assertion that the precautionary principle, utilized by the EU, should be specifically defined and not be misused as the protectionism method, which might restrict trade to defend the country's interests and benefits.<sup>48</sup> Evaluating criticisms on both types of policies are helpful in finding a middle ground and in closing the gap that still exists between the US and EU on GMO regulations.

#### C. Current international laws related to GMOs

The *Convention on Biological Diversity* ("CBD") and *Biosafety Protocol* presently function as the main international environmental norms that regard GMOs.<sup>49</sup> Recently, the

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<sup>47</sup> See Du, *supra* note 34, at 391-395 (emphasizing a need for incorporating non-scientific concerns, such as socioeconomic and ethical consideration, into the GMO regulation system, and concludes that these socioeconomic and ethical externalities would be helpful for attaining a public trust).

<sup>48</sup> See Marc Victor, *Precaution of Protectionism?, The Precautionary principle, Genetically Modified organisms, and Allowing Unfounded Fear to Undermine Free Trade*, 14 TRANSNAT'L LAW. 295, 321 (2001).

<sup>49</sup> Currently, the parties of the *CBD* are 194 countries. See UNITED NATIONS TREATY COLLECTIONS, [https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg\\_no=XXVII-8&chapter=27&lang=en](https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=XXVII-8&chapter=27&lang=en) (last visited Apr. 1 2014). Additionally, the parties of the *Biosafety Protocol* are 167 countries. See UNITED NATIONS TREATY COLLECTIONS, [https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg\\_no=XXVII-8-](https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=XXVII-8-)

members of the *Biosafety Protocol* adopted a supplementary protocol (the *Liability and Redress Supplementary Protocol*), dealing with the liability and redress of the damage caused by GMOs in 2010.<sup>50</sup> While *CBD* and *Biosafety Protocol* are international environmental laws, WTO related provisions deal with international trade laws for disputes regarding GMO trade. This section will discuss the key provisions and details for each international environmental and trade law to further discuss domestic GMO regulations throughout the US, EU, and South Korea.

## 1. International environmental laws

### a. CBD (Convention on Biological Diversity)

The *CBD* was adopted on March, 1992 in Nairobi, Kenya.<sup>51</sup> The *CBD* deals with the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources.<sup>52</sup>

*CBD* Article 8(g) stipulates that each contracting party “shall establish or maintain means to regulate, manage, or control risks associated with the use and release of living modified organisms.”<sup>53</sup> There is also another duty under the Article 19 (4) to “provide any available information about the use and safety regulations required by that contracting party

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a&chapter=27&lang=en (last visited Apr. 1, 2014).

<sup>50</sup> *The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety*, CONVENTION ON BIOLOGICAL DIVERSITY, <http://bch.cbd.int/protocol/supplementary/> (last visited Mar. 26, 2014).

<sup>51</sup> *History of the Convention*, CONVENTION ON BIOLOGICAL DIVERSITY, <http://www.cbd.int/history> (last visited Mar. 7, 2014).

<sup>52</sup> See Gretchen L. Gaston & Randall S. Abate, *The Biosafety Protocol and the World Trade Organization: Can The Two Coexist?*, 12 PACE INT’L L. REV. 107, 110 (2000).

<sup>53</sup> See Karen M. Graziano, *Biosafety Protocol: Recommendations to Ensure the Safety of the Environment*, 7 COLO. J. INT’L ENVTL. L. & POL’Y 179, 195 (1996).

in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the contracting party into which those organisms are introduced.”<sup>54</sup> In addition, the *CBD* Article 19 (3) imparts a duty upon the parties involved to consider the need for a protocol, which has led to the *Biosafety Protocol* and the most key provision, Advanced Informed Agreement (AIA).<sup>55</sup>

b. Biosafety Protocol (Cartagena Protocol on Biosafety)

While the *CBD* takes an important legal step for protecting the intrinsic value of biological diversity, *Biosafety Protocol* aims to establish an adequate level of protection in the field of the safe transfer, handling, and use of GMOs as a protocol of *CBD*.<sup>56</sup> The *Biosafety Protocol* especially focuses on the transboundary movement of GMOs and was adopted in Montreal, Canada, in January 29, 2000. This treaty took effect in September 11, 2003.<sup>57</sup>

The most salient provision of the *Biosafety Protocol* is the AIA, provided in Aarticle 7-13. The AIA is mainly comprised of notification, acknowledgement, and risk assessment procedures. Under these articles, the exporting party that wishes to place GMOs into international trade must notify the importer’s national authority prior to the first shipment. The importing party must then acknowledge receipt of the notification.<sup>58</sup> In addition, the

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<sup>54</sup> See *Id.*

<sup>55</sup> See Gareth W. Schweizer, *The Negotiation of the Cartagena Protocol on Biosafety*, 6 ENVTL. LAW. 577, 590-591 (2000).

<sup>56</sup> See Timothy Josling, *International Institution, World Trade Rules, and GMOs*, in GENETICALLY MODIFIED ORGANISMS IN AGRICULTURE –ECONOMICS AND POLITICS 127 (Gerald C. Nelson ed., 2001); Darren Smits & Sean Zaboroski, *GMOs: Chumps or Champs of International Trade*, 1 ASPER REV. INT’L BUS. & TRADE L. 111, 124 (2001).

<sup>57</sup> *The Cartagena Protocol on Biosafety*, CONVENTION ON BIOLOGICAL DIVERSITY, <http://bch.cbd.int/protocol/> (last visited Mar. 27, 2014).

<sup>58</sup> See Brett Grosko, *Genetic Engineering and International Law: Conflict or Harmony? An Analysis of the Biosafety Protocol, GATT, and the WTO Sanitary and Phytosanitary Agreement*, 20 VA. ENVTL. L.J. 295,

*Biosafety Protocol*, Article 15 refers to the exporting nations' obligations to undertake risk assessments based on scientific evidence.<sup>59</sup> After these procedures, the importing party has the right to decide whether or not to import the GMOs from the exporting party. Besides these provisions, National Focal Point (NFP), Competent National Authority (CNA), and Biosafety Clearing House are other key provisions that connect contracting parties and share information about GMO regulations.<sup>60</sup>

Article 18 and Article 27 of the *Biosafety Protocol* addresses the GMO labeling and GMO liability systems. Article 18 requires each party to take measures for labeling GMOs within three categories: (1) GMOs intended for direct use as food or feed, or for processing, (2) GMOs for contained use, and (3) GMOs for intentional introduction into the environment. On the other hand, Article 27 states that the parties meeting to negotiate shall adopt a process regarding liability and redress within four years.

The *Biosafety Protocol* also takes on the precautionary principle, which is the fundamental concept in international environmental law and policy. The precautionary approach is expressed in the preamble of the *Biosafety Protocol* and Article 1 provides an interpretation in accordance with the precautionary approach.<sup>61</sup>

### c. Liability and Redress Supplementary Protocol

The original *Biosafety Protocol* provides a liability and redress concept in Article 27.

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303 (2001); Schweizer, *supra* note 55, at 598-599.

<sup>59</sup> Under the Article 15(1), the risk assessment "shall be carried out in a scientifically sound manner." However, there is no definition or international agreement on this phrase. It may cause different interpretation among countries. See MACKENZIE ET AL, *supra* note 24, at 107. Furthermore, the *Biosafety Protocol* Article 16 provides the requirements for risk management. See MACKENZIE ET AL, *supra* note 24, at 111,

<sup>60</sup> The National Focal Point (NFP) and Competent National Authority (CNA) are provided in Article 19. Additionally, The Biosafety Clearing House (BCH), which is an information exchange mechanism for the implementation of the *Biosafety Protocol*, is provided in Article 20. See *Id.* at 129-136.

<sup>61</sup> See Grosko, *supra* note 58, at 304.

To comply with this, the *Liability and Redress Supplementary Protocol* was adopted on October, 2010. Even though there is no affiliated protocol about GMO labeling under the *Biosafety Protocol*, it is encouraging that the supplementary protocol was concluded regarding GMO liability and redress system. However, the divided negotiation groups were in debates during the discussions and there still remain many international and national loopholes that need to be solved. The specific contents of this protocol and future issues will be examined in Section IV.

## **2. International trade laws (WTO and related provisions)**

The WTO is the largest international trade organization and was established to ensure free trade between countries. Many WTO related provisions, such as the General Agreement on Tariffs and Trade (GATT), SPS Agreement, and the Agreement on Technical Barriers to Trade (TBT Agreement), function as standards to regulate international trade. The US emphasizes the observance of the WTO provisions as the biggest exporting country of GMOs. First, the GATT related provisions, which deal with special situations about GMO trades, are founded in the Article 3, 11 and 20 (b). Under the GATT Article 3, the exporting party might make a violation claim towards the opposing party for the Most Favored Nation (MFN) treatment.<sup>62</sup> GATT Article 11 also provides quantitative restrictions and the exporting party could argue that the opposing party violated this provision. However, exceptions are provided under Article 20, which justifies the violation under certain conditions.

In addition to GATT provisions, the SPS Agreement and TBT Agreement could be applied to GMO trade regulations. These agreements deal with trade restrictive measures on

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<sup>62</sup> See *Id.* at 307.

human, animal or plant health, and technical regulations that include safety standards or labeling requirements. The SPS Agreement, strengthening GATT Article 20's exceptions, can be issued when there is a problem with the GMO bans by the EU against the US.<sup>63</sup> Also, the TBT Agreement is relevant to the GMO labeling system.<sup>64</sup> The TBT Agreement provides "labeling" as one of the technical regulations under its Annex 1. Therefore, the GMO labeling requirements could be addressed under the TBT Agreement.

#### **D. US, EU, and South Korea's perspectives and domestic laws for GMO**

The different approaches and philosophies on GMOs (explained in Section A) are reflected in their interpretation and participation of the international environmental laws, which were reviewed in Section B. Both the EU and South Korea are contracting parties of the *CBD* and *Biosafety Protocol*, making them implement GMO regulations. On the contrary, the US has not yet ratified the *CBD* and has not even signed the *Biosafety Protocol*, making US regulation the most lenient. These different attitudes by the US, EU and South Korea is also apparent in the domestic implementation and regulation of GMOs. This section will address each country's domestic laws and assess the big gap in GMO regulations to compare each country's perspective.

##### **1. US regulation of GMO**

Because the US is not a party of the *CBD* and *Biosafety Protocol*, these treaties are not binding authorities to the US. Unlike the EU and South Korea, the US does not have a

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<sup>63</sup> See Daniel Schramm, *The Race to Geneva: Resisting the Gravitation Pull of the WTO in the GMO Labeling Controversy*, 9 VT. J. ENVTL. L. 93, 106 (2007).

<sup>64</sup> See Applegate, *supra* note 30, at 237.

comprehensive legislation about GMOs and relies on preexisting laws and agencies.<sup>65</sup> There are three primary federal agencies to regulate GMOs in the US: the United States Department of Agriculture (USDA), the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA).<sup>66</sup> These three agencies have their own regulation field, and also cooperate with each other in order to regulate GMOs.

The USDA regulates Genetically Modified (GM) crops under the *Federal Plant Pest Act* (FPPA) and the *Plant Protection Act* (PPA). Therefore, certain GM crops are classified as biological control organisms. The Animal and Plant Health Inspection Service (APHIS) also plays an important role under the USDA. Before GM crops are moved or field-tested, the APHIS must be notified.<sup>67</sup>

The second federal agency is EPA, which regulates the environmental risk-producing activities. Under the EPA, GM plants are regulated through the *Federal Insecticide, Fungicide and Rodenticide Act* (FIFRA) and *Toxic Substances Control Act* (TSCA). The FIFRA regulates plants that have been genetically engineered to have pesticide qualities.<sup>68</sup> For example, once a *Bacillus thuringiensis* (*Bt*) corn is introduced, the EPA assesses the risk of the *Bt* corn in regards to pesticide qualities of the materials that the *Bt* corn has or emits. Under the TSCA, the EPA has the authority to regulate GM microorganisms.

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<sup>65</sup> See Marc Firestone, *A Quick Look at Two Areas of Doctrinal Difference Between EU and U.S. Decision Makers*, 20 TUL. J. INT'L & COMP. L. 1, 31-32 (2011).

<sup>66</sup> For a comprehensive understanding of the US GMO regulatory system by government agencies, see generally PIFB report, *supra* note 35. Additionally, for the detailed regulatory explanation of these three agencies, see Mary Jane Angelo, *Regulating Evolution for Sale: An Evolutionary Biology Model for Regulating the Unnatural Selection of Genetically Modified Organisms*, 42 WAKE FOREST L. REV. 93 (2007).

<sup>67</sup> See Mystery Bridgers, *Genetically Modified Organisms and the Precautionary Principle: How the GMO Dispute Before the World Trade Organization could decide the Fate of International GMO Regulation*, 22 TEMP. ENVTL. L. & TECH. J. 171, 176 (2004).

<sup>68</sup> The pesticide qualities, called biopesticides, include toxicology and allergenicity. It was tested on more than 10 acres and the EPA regulates genetically engineered plants on the basis of the testing result. The EPA also sets limits for the amount of pesticides that are allowed in a product, based on product characterization, allergenicity, potential pest resistance, etc. *See Id.* at 177.

The final federal agency is FDA, which was established to protect human health. The FDA has the authority and responsibility for food safety issues that may be raised by GM foods. For example, in case of the food made by *Bt* corn, the FDA evaluates the allergenicity or toxicity of the GM food. As for the GM food regulation, the FDA generally recognizes GM food as safe. Therefore, it is subject to regulation only when a food substance is so altered that the substance is generally recognized as unsafe.<sup>69</sup> Under the FDA, there are many laws related to GMO regulations. The *Federal Food, Drug, and Cosmetic Act* (FFDCA) is the primary law regarding GMOs and the *Public Health Service Act* (PHSA) is another relevant law.

These three US agencies, participating in regulating GM crops, plants, and foods, do not enforce pre-market review and approval, except for a food additive regulation under the FDA.<sup>70</sup> This lack of a central regulation system shows how lenient the US GMO regulation is.

## **2. EU's implementation**

The EU has adopted many directives and regulations about GMOs after the EU became a contracting party of the *CBD* and *Biosafety Protocol* in 1993 and 2003, respectively. The *Directive 90/219/EEC* regulates the contained use of GMOs and the EU has adopted the *Directive 2001/18*, the main regulation system on the deliberate release into the environment

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<sup>69</sup> See Julie Teel, *Regulating Genetically Modified Products and Processed: An Overview of Approaches*, 8 N.Y.U. ENVTL. L.J. 649, 664-665 (2000).

<sup>70</sup> See Donald L. Uchtman, *Agricultural Biotechnology Regulation: The Pew Initiative and Its Stakeholder Forum*, 9 DRAKE J. AGRIC. L. 53, 60 (2004).



of GMOs, on March 2001.<sup>71</sup> This EU Directive addresses the placing of GMOs on the market, as well as the release of GMOs to the environment. The first reform of *Directive 2001/18* took place between 2001 and 2003. This reform resulted in the *Regulation 1829/2003*, a new legislation on GM food and feed<sup>72</sup>. The EU also established a prior-authorization for GM products by the European Food Safety Authority (EFSA), where the purpose is to conduct a scientific risk assessment of GM food and feed.<sup>73</sup>

In addition, the EU regulates the intended transboundary movement, which is the main focus of the *Biosafety Protocol*. The EU enacted the *Regulation 1946/2003* for transboundary movement of GMOs as an implementation of the *Biosafety Protocol*.<sup>74</sup> Since the EU already has the *Directive 2001/18* that includes the AIA (found under the *CBD*) for GMO imports, the *Regulation 1946/2003* focuses on the procedures for GMO exports. The EU also has the *Regulation 1830/2003* for controlling GMO labeling and traceability. The system includes traceability, as well as labeling, and proves how strict the EU's system is. The EU's strong regulation on GMO labeling will be further addressed in Section III.

Recently, the European Commission proposed a new reform to allow a Member State to restrict the cultivation of GMOs in 2010. There exist a lot of pro and cons regarding this 2010 proposal currently in the EU.<sup>75</sup> Known from many directives and regulations, the EU

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<sup>71</sup> Directive 2001/18/EC, 2001 O.J. (L 106)

<sup>72</sup> Regulation 1829/2003 2003 O.J. (L 268).

<sup>73</sup> See Grossman, *supra* note 22, at 339. See also Arpad Pusztai & Susan Bardocz, *Potential health effects of Foods Derived from Genetically Modified (GM) Plants – What are the Issues?*, in BIOSAFETY FIRST - HOLISTIC APPROACHES TO RISK AND UNCERTAINTY IN GENETIC ENGINEERING AND GENETICALLY MODIFIED ORGANISMS 239, 239 (Terje Traavik & Lim Li Ching eds., 2007).

<sup>74</sup> See Margaret Rosso Grossman, *Traceability and Labeling of Genetically Modified Crops, Food, and Feed in the European Union*, 1 J. FOOD L. & POL'Y 43 (2005).

<sup>75</sup> For a favorable evaluation, See Maria Weimer, *What Price Flexibility? - The Recent Commission Proposal to Allow for National "Opt-Outs" on GMO Cultivation under the Deliberate Release Directive and the Comitology Reform Post-Lisbon*, 1 EUR. J. RISK REG. 345 (2010). But see Laura Moore Smith, *Divided We Fall: The shortcomings of the European Union's Proposal for Independent Member States to Regulate the Cultivation*

has taken very strict policies on GMO regulation and maintained that stance, taking note the possible risk on GMOs.

### 3. South Korea's implementation

South Korea enacted the *LMO Act* in order to implement the *Biosafety Protocol* in 2001.<sup>76</sup> It took seven years for this *LMO Act* to be effective due to the many debates between agencies and a lack of consensus in public opinions.<sup>77</sup> The *LMO Act* of South Korea addresses not only the import and export of GMOs, but also the development, production and risk assessment. One of the main provisions is Article 8. The *LMO Act* Article 8 first provides an authorization procedure, where the authorization by a minister of the concerned administrative agency is required for a person to import GMOs.<sup>78</sup> When GMOs or GM products are imported, the prior approval (a requirement in South Korea) is a precautionary measure by the government.<sup>79</sup> South Korea's *LMO Act* reflects the main provisions of the *Biosafety Protocol* that helps implement the conditions within the *Biosafety Protocol*.<sup>80</sup>

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*of Genetically Modified Organisms*, 33 U. PA. J. INT'L. 841 (2012) (expressing a negative evaluation to the new EU proposal).

<sup>76</sup> See JongYeong Lee, *Domestic Legislative Framework and Improvement Plan, the Cartagena Protocol on Biosafety*, 27-1 CHUNGANGBEOPHAK [ChungAng Law Review] (2003). The *LMO Act* was passed in February 28, 2001. An additional clause of the *LMO Act* prescribed that "this Act shall enter into force from the date when the *Biosafety Protocol* comes into force in the Republic of Korea." However, it was not until December, 2007 that the South Korea ratified the *Biosafety Protocol*. Therefore, as of January 1, 2008, both the *Biosafety Protocol* and Korean *LMO Act* became into effect simultaneously in South Korea.

<sup>77</sup> See WonSeog Park, *Comparative Analysis of Regulatory Approaches to LMO/GMO*, 12-1 CHUNGANGBEOPHAK [ChungAng Law Review] 262 (2010).

<sup>78</sup> *Laws and Regulations*, KOREA BIOSAFETY CLEARING HOUSE, <http://www.biosafety.or.kr/english/laws/The%20Act%20on%20Trans-boundary%20Movements%20of%20Living%20Modified%20Organisms.pdf> (last visited Mar. 19, 2014).

<sup>79</sup> See JongYeong Lee, *A system of LMO Act, the implementation law of Biosafety Protocol*, 3-1 BAIOSIPEUTI JEONEOL [Biosafety Journal] 34 (2002).

<sup>80</sup> According to implementation of the *Biosafety Protocol*, the *LMO Act* put "Ministry of Foreign

The problem of GMO regulation in Korea is due to the great number of GMO regulation agencies. South Korea assorts GMOs as agency-related and not by the characteristics of GMOs itself. In South Korea, there are six involved governmental agencies<sup>81</sup>, and the GMOs are categorized by the administrative department (e.g., GMOs used in the Ministry of Commerce, Industry and Energy, GMOs used in the Ministry of Agriculture & Forestry, and GMOs used in the Ministry of Science & Technology). This categorization is not consistent with the categorization of GMOs under the *Biosafety Protocol*. Another serious problem is that the concerned minister of an administrative agency delegates the relevant tasks to a lower agency, increasing the number of agencies involved once again. As a result, there are over ten agencies related to GMO regulation.<sup>82</sup> Therefore critics state that there are too many unnecessary related agencies for GMO regulations, and the complexity of this GMO regulation system in South Korea might cause confusion among the agencies.<sup>83</sup>

The *LMO Act* of South Korea has specific provisions for labeling policies in Article 24. This is similar to EU's regulations, even though the specific contents are different. South Korea has not yet enacted domestic legislation as an implementation of the *Liability and Redress Supplement Protocol*. On the other hand, the *Directive 2001/18* in the EU does not

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Affairs and Trade" as the National Focal Point (NFP) and put "Ministry of Commerce, Industry and Energy" as the Competent National Authority (CAN), which are provisions related to the *Biosafety Protocol*.

<sup>81</sup> The six involved governmental agencies are (1) Ministry of Commerce, Industry and Energy, (2) Ministry of Agriculture & Forestry, (3) Ministry of Environment, (4) Ministry of Health & Welfare, (5) Ministry of Science & Technology, and (6) Ministry of Maritime Affairs & Fisheries.

<sup>82</sup> See Park, *supra* note 77, at 283-286 (mentioning that administrative organization of GMO regulation in South Korea, such as authorization, designation of risk assessment institution, and notification of the results, is too complex and excessive).

<sup>83</sup> For example, Minister of Agriculture & Forestry could delegate its duty to four different departments, according to the GMOs used for agriculture, GMOs used for seed, GMOs used for feed, and GMOs for imports respectively. See *Id.* at 282.

address a liability scheme.<sup>84</sup> Likewise, the Korean *LMO Act* does not provide the liability system but only states in Article 34 the necessity for funds in case damages are caused by GMOs.

It can be said that South Korea has taken efforts to implement the *Biosafety Protocol*. However, South Korea has an excessive amount of government agencies, making the regulation inefficient. In addition, the South Korea's substantial GMO regulations do not meet the EU's standards until now.

#### **E. The necessity for GMO regulations**

As seen in the domestic laws and policies, the three countries' attitudes differ widely, and international conferences that sought solutions for the Protocol related to GMOs were difficult to negotiate because of these conflicting interests. In order to persuade many sides and establish a reasonable regulation of GMOs, a premise for the exact risk assessment for GMOs should be recognized. However, the current situation shows that there is a low certainty and low consensus on GMO risk assessment.<sup>85</sup> Therefore, the next step should be to review whether the GMO regulation is necessary under current scientific uncertainty. Before doing this, the EC-Biotech case will be addressed as an international case to show the legal disputes about GMOs and to demonstrate the significance of regulating GMOs.

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<sup>84</sup> See Grossman, *supra* note 74, at 75.

<sup>85</sup> See Kaare M. Nielsen & Anne Ingeborg Myhr, *Understanding the Uncertainties Arising from Technological Interventions in Complex Biological Systems: The Case of GMOs*, in BIOSAFETY FIRST –HOLISTIC APPROACHES TO RISK AND UNCERTAINTY IN GENETIC ENGINEERING AND GENETICALLY MODIFIED ORGANISMS 116 (Terje Traavik & Lim Li Ching eds., 2007).

## 1. The EC-Biotech case analysis and evaluation on GMO disputes

Reviewing the EC-Biotech case is important because this is the only case that directly addresses the GMO disputes. Through this case, the conflict between the international trade laws and environmental laws was identified. This section will analyze and evaluate the EC-Biotech case. Because the situation has not fully been solved, this section will suggest reasonable directions for dealing with GMO issues after reviewing the results of GMO benefits and risks.

### a. The EC-Biotech case

The EC-Biotech case was about the European Commission's trade measures, banning GMO imports. The US, Canada, and Argentina filed a complaint against the EC's moratorium on the approval of biotech products in August 2003. The WTO panel issued a report on the EC-Biotech case in September 2006 after a long dispute on resolution mechanisms.<sup>86</sup> The panel concluded that the EC's general moratorium and the product-specific approval delays resulted in an "undue delay," violating Article 8 and Annex (C)(1)(a) of the SPS Agreement.<sup>87</sup> The panel also found that the individual EC member states' safeguard measures, prohibiting specific GM products, violated Article 5.1 of the SPS Agreement by failing to conduct risk assessments.<sup>88</sup> The EC decided not to appeal this panel report. The EC-Biotech case shows the apparent conflict between GMO trade parties on an international level.

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<sup>86</sup> Panel Report, *European Communities-Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291, WT/DS292, WT/DS293 (Sep. 29, 2006).

<sup>87</sup> See Carmen G. Gonzalez, *Genetically Modified Organisms and Justice: The International Environmental Justice Implications of Biotechnology*, 19 GEO. INT'L ENVTL. L. REV. 583, 616 (2007).

<sup>88</sup> See *Id.*

b. Evaluation and problems of the EC-Biotech case

The results of the EC-Biotech case are problematic. The EC-Biotech case did not approach the substantial issues, such as whether the GMOs are a risk to humans and the environment, or whether GM products are in “like product” relationship with non-GM products.<sup>89</sup> The WTO will be forced to answer these issues because the WTO evaded answering the important issues on GMOs during this case. Additionally, in the near future, there is a possibility for issues regarding labeling, since the EC-Biotech case did not deal with labeling system.

The main problem is that the WTO panel drew a conclusion by using only WTO rules. Therefore, the precautionary principle, which is reflected in the *Biosafety Protocol*, was not accepted to solve GMO issues relevant to GMO trades by the WTO panel. In the EC-Biotech case, the EU had argued that the *CBD* and *Biosafety Protocol* should be taken into account when trying to ban GMO imports from the US. However, the panel rejected the argument and concluded that these treaties were not binding on all member countries.<sup>90</sup> The fact that the WTO panel was dismissive of the environmental treaties, such as the *CBD* and *Biosafety Protocol*, and missed an opportunity to embrace the precautionary principle might have weakened the WTO’s authority.<sup>91</sup>

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<sup>89</sup> See BongSuk Sung, *The Analysis of WTO Panel’s Decision on Trade Dispute about Biotech Product*, 32-1 MUYEOKHAKHOEJI [Trade Law Journal] 301 (2007).

<sup>90</sup> A critical opinion of the WTO panel decision states that “what is missing from international trade conflict solution is a mechanism to allow these differing national regulatory regimes to be reconciled.” It also mentioned that “the challenge for the SPS Agreement (and the WTO) is to move beyond the strict wording of the Agreement to reflect how it can accommodate the complexities arising from divergent national regulation.” See Joseph McMahon, *The EC-Biotech Decision: Another Missed Opportunity?*, in *THE REGULATION OF GENETICALLY MODIFIED ORGANISMS: COMPARATIVE APPROACHES* 354 (Luc Bodiguel & Michael Cardwell eds., 2010).

<sup>91</sup> See Debra M. Strauss, *Feast or Famine: The Impact of the WTO Decision Favoring the U.S. Biotechnology Industry in the EU Ban of Genetically Modified Foods*, 45 AM. BUS. L.J. 775 (2008) (criticizing

c. Tension between the trade and environmental treaties

The EC-Biotech case did not propose a clear solution on the conflicts between the WTO rules and *Biosafety Protocol*. The tension that currently exists now between the trade and environmental treaties is bound to become an issue in the future. This conflict and tension is caused by not having any provision on which the treaty overrules the other one. If the *Biosafety Protocol* had stated which provision had priority over the other, there would have been no problems. However, it is not apparent on how to decide which provision overrules the other from the current articles of the *Biosafety Protocol*. The WTO related provisions do not stipulate the priority between the international environmental treaties and SPS Agreement articles. Therefore, the relations between the international environmental norms and trade norms need to be resolved in how they interpret and prioritize the provisions.

Some argue that the WTO system is a better way to manage GMOs than the *Biosafety Protocol* from the perspective in favor of a more moderated, risk-based regulatory scheme. On the other hand, some argue that health and environmental concerns should be considered more in depth before the WTO. If there is a provision to reflect another treaty's principle, it should be carefully considered so that both treaties reduce conflicts and harmonize with each other.<sup>92</sup> As a universal international treaty, the *Vienna Convention on the Law of Treaties* allows a treaty interpretation method that does not exclude other existing treaties. Therefore, future provisions should aim for reducing the conflicts caused by excluding existing treaties by interpreting the international norms equally, similar to the

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that the WTO panel decision has a negative effect on developing countries, as well as weakening the WTO's authority).

<sup>92</sup> See JungWon Park, *A Critique of the EC v. Biotech Case with Special Reference to the Problem of Treaty Interpretation*, 19-3 HANYANGBEOPHAK [HanYang Law Review] 193-196 (2008).

*Vienna Convention on the Law of Treaties*.<sup>93</sup> For example, the SPS Agreement Article 5.7 reflects the precautionary principle. Therefore, Article 5.7 under the SPS Agreement should be considered positively and should be broadly interpreted in the WTO.<sup>94</sup>

## **2. Reasons for needing GMO regulations**

### **a. The benefits and risks of GMO development**

Scholars and scientists have done a lot of research and experiments for more than 15 years since the initial development of GMOs. In order to decide if GMO regulations are necessary, it is important to look at the opposing sides in regards to the development of GMOs. Proponents of GMOs point out benefits from the modern technology techniques. First, GMOs are able to expand the productive capacity and feed the growing human populations. Second, GMOs could reduce the use of pesticides and herbicides and it would be beneficial to the environment.<sup>95</sup> Third, the supporters of GMOs say that the biogenetically altered organisms help increase disease resistance, reduce bruising tolerance, and elevate herbicide tolerance.<sup>96</sup>

On the other hand, opponents warn about the potential threats of GMOs based on several factors. First, the rapid biotechnology development disrupts the ecosystems and

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<sup>93</sup> See Strauss, *supra* note 91, at 798.

<sup>94</sup> See Applegate, *supra* note 26, at 52.

<sup>95</sup> See Grosko, *supra* note 58, at 299.

<sup>96</sup> See Graziano, *supra* note 53, at 184. Also, there is an opinion that GM crops could help human health, by lessening vitamin A deficiency. See FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS [FAO], ETHICS SERIES 2, GENETICALLY MODIFIED ORGANISMS, CONSUMERS, FOOD SAFETY AND THE ENVIRONMENT 18 (2001) [hereinafter FAO ETHICS SERIES].



underpins the evolutionary and ecological stability, such as weed proliferation.<sup>97</sup> Second, uncontrolled biotechnology can result in health problems. There is a risk of creating new viruses and mutations, which could be toxic, allergenic, or dangerous to humans.<sup>98</sup> Finally, GMO skeptics worry about the adverse effects on non-target crops where conventional crops could be pollinated unintentionally by GM crops by wind or insects.<sup>99</sup>

Under current circumstances, the claims on whether or not GMOs have a risk are in direct opposition. It seems that there is not enough scientific evidence to substantially verify the risk, which is also known as scientific uncertainty. However, the scientific reports and evidence supporting the risk of GMOs are continually being discovered.

b. Growing need for GMO regulations

The need for GMO regulations can be easily justified with experimental and practical results, which prove the harms of GMOs to humans and the environment. The results show that the GMOs are a risk to humans and the environment, even in the US (a country very favorable to GMO development). In the recent two-year long study by US scientists, they found that GM corn-fed rats developed tumors and many other health problems.<sup>100</sup> Additionally, in the Ecological Society of America conference, researchers stated that GM canola has been found thriving in the wild for the first time in parts of North Dakota.<sup>101</sup>

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<sup>97</sup> See Richard Caplan, *GMOs in Agriculture: An Environmentalist Perspective*, in GENETICALLY MODIFIED ORGANISMS IN AGRICULTURE –ECONOMICS AND POLITICS 200 (Gerald C. Nelson ed., 2001).

<sup>98</sup> See Graziano, *supra* note 53, at 185-188. See FAO ETHICS SERIES, *supra* note 96, at 17.

<sup>99</sup> See Grosko, *supra* note 58, at 301; Michael Faure & Andri Wibisana, *Liability for Damage Caused by GMOs: An Economic Perspective*, 23 GEO. INT'L ENVTL. L. REV. 1, 9 (2010); Caplan, *supra* note 97, at 200.

<sup>100</sup> *GMO Foods Are More Harmful Than You Think*, BEWELLBUZZ (Sep. 26, 2012), <http://www.bewellbuzz.com/featured/gm-foods/>

<sup>101</sup> See Natasha Gilbert, *GM crop escapes into the American Wild: Transgenic Canola found growing freely in North Dakota*, NATURE (Aug. 6, 2010),

Another important thing to consider when looking at the necessity of GMO regulation is the consequences in using GMOs for future generations.<sup>102</sup> GMO development is a relatively recent emergence of GM technology and the extremely limited knowledge requires an evaluation of the potential risks.<sup>103</sup> In addition, many countries are continually trying to develop new GMOs and GM products (e.g., GM fish or GM insects) beyond the current limited GMOs, such as corn, tomato, or soybean.<sup>104</sup> If the risks caused by the new GMO developments are not recognized in a timely fashion, the effects would be irreversible. Therefore, the risk of GMOs should be carefully observed and regulations are needed for the current and future GMOs.

GMO labeling and liability systems are preventive measures and these systems are different from the GMO risk assessment and GMO import or export authorization. GMO labeling and liability systems are needed internationally and domestically, since substantial scientific certainty is not a prerequisite for these systems. All these things considered, the GMO regulation is necessary and a stricter regulatory framework in the GMO labeling and liability systems is required to prepare for GMO risks and create strong foundations for a legal framework.<sup>105</sup>

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<http://www.nature.com/news/2010/100806/full/news.2010.393.html> (last visited Jan. 12, 2014).

<sup>102</sup> See Stephen McCaffrey, *Biotechnology: Some Issues of General International Law*, 14 TRANSNAT'L LAW. 91, 101 (2001).

<sup>103</sup> See Angelo, *supra* note 66, at 110.

<sup>104</sup> See MACKENZIE ET AL., *supra* note 24, at 9-10.

<sup>105</sup> This paper addresses the liability and redress system for environmental damages or human health damages caused by GMOs. It does not focus on the damages caused by GMO labeling, such as mislabeling. However, both systems could be interrelated in that the exact GMO labeling will be helpful for determining the compensation for the damage caused by GMOs under the GMO liability system.

### **3. Summary**

It is difficult to declare that GMOs are dangerous by looking at past scientific evidence. However, there have been more accumulated reports and scientific experiments showing that GMOs have potential risks to humans and the environment. From the EC-biotech case, future conflicts between international trade laws and environmental ones are inevitable. When a case is brought to the WTO, the panel should consider the environmental norms as well as WTO rulings. Furthermore, the GMO regulatory systems are necessary, given the characteristics of potential and irreversible risks by GMOs. The GMO labeling and liability systems are very controversial, but essential for the future regulation framework.

## **III. GMO labeling system from the EU, US, and South Korea's policies**

### **A. Current international and domestic regulations**

The different approaches and principles toward the GMOs are shown in the GMO labeling regulations, which reflect the principles mentioned above.<sup>106</sup> The US does not compel specific labeling for products containing GMOs, even though the US permits GMO labeling on a voluntary basis. On the other hand, the main GMO imports countries, the EU and South Korea, have shown to favor the GMO labeling system. Currently, about 20 countries (including the EU, South Korea, Japan, Australia, and New Zealand) are enforcing the mandatory labeling system. However, different standards or details in legislations and policies among the countries exist, leading to many debates on the labeling system itself, the

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<sup>106</sup> See FAO ETHICS SERIES, *supra* note 96, at 16.

specific methods of labeling, and its consistency with international trade laws (which will be discussed later in B and C). Before approaching the debates, it is necessary to review the existing international regulations, focusing on GMO labeling and domestic regulations in the EU, US, and South Korea

## **1. Existing international GMO labeling regulations**

### *a. CBD and Biosafety Protocol*

The *CBD*, an international environmental treaty, does not directly mention GMO labeling and just broadly states that the contracting party should establish regulations on GMO risks. The labeling system is provided in Article 18 of *Biosafety Protocol*.<sup>107</sup> Article 18.1 provides that each party shall take measures to require living modified organisms to be handled, packaged, and transported under conditions of safety considering relevant international rules and standards.<sup>108</sup> Under *handling, transport, packaging*, Article 18.2 contains specific and detailed provisions regarding direct GM food or feed, contained use of GMOs, and intentional introduction into the environment of GMOs in Article 18.2(a), 18.2(b) and 18.2(c) respectively.<sup>109</sup>

Focusing on Article 18.2(a) for GM food or feed, it states that each party shall clearly identify through accompanied documentation whether they may contain living modified organisms, had no intention for introduction into the environment, and additional contact

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<sup>107</sup> See MACKENZIE ET AL, *supra* note 24, at 123.

<sup>108</sup> See *Id.* at 124.

<sup>109</sup> See *Id.* at 125.

information for further inquiries.<sup>110</sup> There was no consensus for this international regulation system for GMO labeling until the *Biosafety Protocol*. However, even though this protocol was concluded and called for an international regulation system, the contents of GMO labeling standards has not been specified and no international guideline has been made for now.

b. The WTO related provisions

The SPS Agreement and TBT Agreement are WTO related provisions and do not provide requirements or standards of GMO labeling. Instead, the WTO related provisions propose that the GMO labeling regulations of each country would not constitute a restriction on international trade. While the SPS Agreement Article 2.1 recognizes the right to take measures for protection of human health, Article 2.2 also provides that the measures restricting trade of GMOs shall be based on scientific principles and not discriminate between members arbitrarily or unjustifiably. This means that GMO labeling measures have to have scientific reason in order to prove the danger of GMOs when the labeling measure is pertinent to the SPS measure.<sup>111</sup> Additionally, the TBT Agreement states that technical regulations, such as labeling, shall not create unnecessary obstacles to international trade under Article 2.2.<sup>112</sup>

As mentioned above, the different legislative intent between international environmental laws and trade laws could be found within current GMO labeling regulation.

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<sup>110</sup> The issue on the documentation requirements for GMOs used as *food or feed*, or for *processing* was very controversial. Some countries were concerned that a clear identification requirement would impose costly segregation or identity preservation obligation. However, Article 18.2(a) avoids this issue by providing documentation identifying that they “may contain” GMOs. *See Id.* at 126-127.

<sup>111</sup> *See* ANDREW T. GUZMAN & JOOST H.B. PAUWELYN, INTERNATIONAL TRADE LAW 532 (2d ed. 2012).

<sup>112</sup> *See Id.* at 575.

For example, an exporting country (i.e., the US) could raise the issue that GMO labeling regulations of an importing country do not meet the requirement of the SPS or TBT Agreement. However, the importing country (i.e., the EU) could prove that they meet the requirements of the SPS or TBT Agreement provisions. This would ultimately lead to conflict and specific issues will be addressed later on under the discussion of WTO consistency.

## **2. EU's approach to the labeling system**

The EU's labeling system is the strictest in the world since its regulation scope of GMO labeling is broad and detailed.<sup>113</sup> In order for consumers to make an informed choice, the EU adopted two main regulations: *Regulation 1829/2003* and *Regulation 1830/2003*.<sup>114</sup> Under the *Regulation 1829/2003 on GM food and feed*, food products produced from GMOs should be labeled regardless of whether or not the DNA containing GM content could be found in the final product.<sup>115</sup> Additionally, the *Regulation 1830/2003 on the traceability and labeling of GMOs* calls for traceability of GMOs and the monitoring system where food production industries should comply to indicate the presence of GMOs.<sup>116</sup> This is different from South Korea's more relaxed labeling system, proving that the EU has the most rigorous labeling system.

However, the EU does recognize that unavoidable adventitious presence (an unintentional mixture between GM products and non-GM products of GMO material) could

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<sup>113</sup> See Claudio Mereu, *Schizophrenic Stakes of GMO Regulation in the European Union*, 3 EUR. J. RISK REG. 202 (2012).

<sup>114</sup> See Peter Burchett, *A Castle in the Sky: The Illusory Promise of Labeling Genetically Modified Food in Europe*, 23 PENN ST. INT'L L. REV. 173, 186 (2004).

<sup>115</sup> See *Id.*

<sup>116</sup> See Valery Federici, *Genetically Modified Food and informed Consumer Choice: Comparing U.S. and EU Labeling Laws*, 35 BROOK. J. INT'L L. 515, 543 (2010); Grossman, *supra* note 74, at, 66.

occur. Therefore, the EU established a 0.9 percent threshold for such products.<sup>117</sup> This standard of threshold is very strict compared to other countries' threshold (e.g., the threshold for the adventitious presence of South Korea is 3 percent).

When the threshold is above 0.9 percent, all food containing GMOs are required to be labeled with specific labeling methods according to the EU's labeling system. Organisms that have been "genetically modified" or products that have been "produced from genetically modified (ingredient name)" are labeled if they are above the assigned threshold level. Additionally, the EU utilizes the word "contain" in its labeling system. For example, a product will be labeled as "contain genetically modified (name of organism)" or "contain (name of ingredient) produced from genetically modified (name of organism)."<sup>118</sup> The EU has also established specific provisions according to how a product is packaged (i.e., whether packaged or unpackaged; with a list of ingredients or without a list of ingredients).<sup>119</sup>

From the specific labeling system mentioned above, the EU has coped very well with the risks of GMOs under the Directives and Regulations, using the precautionary principle. On the other hand, this system of the EU has a problem of the possibility of inconsistency with WTO related provisions.

### **3. US approach to the labeling system**

The US enforces a voluntary labeling system and the US government maintains these labeling policies. The US does not require a special labeling system for GM foods under the substantial equivalence principle, which states that there is no difference between GMO and

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<sup>117</sup> See Burchett, *supra* note 114, at 187. See also Federici, *supra* note 116, at 518.

<sup>118</sup> See Burchett, *supra* note 114, at 190.

<sup>119</sup> See Federici, *supra* note 116, at 544-545.

non-GMOs.

As mentioned in Section II, the US regulates the GMOs or GM products with existing laws such as PPA, FIFRA, TSCA, and FFDCA. Among these laws, only the FFDCA sets requirements about food labeling.<sup>120</sup> The FFDCA section 403 authorizes the FDA to regulate food labels.<sup>121</sup> However the FDA does not require a mandatory labeling system and maintains a voluntary labeling system to avoid the possibility of misinforming the consumers.<sup>122</sup> According to the enforcement of voluntary labeling system on GMOs, the FDA requires the labeling of GM foods only if they are different substantially from non-GM products.<sup>123</sup> In other words, the FDA does not mandate GM food labeling, but instead GM foods labeling should be mandatory only if they have shown the significant difference in a way that might pose a risk to consumer, such as a major nutrient change or the presence of allergenicity.<sup>124</sup>

The FDA's lenient attitude on labeling GMOs can be demonstrated in the *1992 Draft Guidance for Industry* called "Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering" and affirmed in *2001 Draft Guidance for Industry* again.<sup>125</sup> The FDA's policy was challenged by a consumer advocate group who wanted stricter labeling systems. However, the District Court rejected the claim that the

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<sup>120</sup> See *Id.* at 539.

<sup>121</sup> See Frank J. Miskiel, *Voluntary Labeling of Bioengineered Food: Cognitive Dissonance in the Law, Science, and Public Policy*, 38 CAL. W. L. REV. 223, 230 (2001).

<sup>122</sup> See JeongSoon Choi, *Law and the Risk Analysis of Genetically Modified Crops in the United States, the European Union, and South Korea: Balancing Market Access with the Protection of Human Health and the Environment* (Jan. 2006) (unpublished S.J.D. dissertation, Indiana University). See also Burchett, *supra* note 114, at 182.

<sup>123</sup> See Burchett, *supra* note 114, at 183.

<sup>124</sup> See Federici, *supra* note 116, at 538.

<sup>125</sup> Debra M. Strauss, *The International Regulation of Genetically Modified Organisms: Importing Caution into the U.S. Food Supply*, 61 FOOD & DRUG L.J. 167, 184 (2006).



FDA's policy statement was arbitrary and capricious, and concluded that the FDA's interpretation of the FFDCA was reasonable.<sup>126</sup>

In spite of the FDA's decision against mandatory labeling, there was a movement for mandatory labeling in some states and they have enacted state laws to require a mandatory GMO labeling system.<sup>127</sup> The movement for a mandatory labeling system has been continued in ten other states, including California (one of the most active states for a mandatory labeling system). California would have been the first state in the US to pass an initiative for a mandatory labeling system for GMOs.<sup>128</sup> Recently, Connecticut and Maine have passed the mandatory labeling laws in a state level. Additionally, Vermont has enacted a statute requiring milk to be labeled as recombinant bovine somatotropin (bST) when produced by treated cows with the growth hormone.<sup>129</sup> This state law was challenged by food producers in the federal court. In *International Dairy Foods Association v. Amestoy*<sup>130</sup>, the second circuit concluded that the law was unconstitutional on the ground that it violated the manufacturers' right not to speak under the First Amendment.<sup>131</sup>

Overall, the US government, federal laws, and courts are still reluctant to enforce a mandatory GMO labeling system. Finally, the labeling system in the US depends on the voluntary will by manufacturing firms because there is no obligation to label GMOs. This is

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<sup>126</sup> See Emily Robertson, *Finding a Compromise in the Debate over Genetically Modified Food: An Introduction to a Model State Consumer Right-To-Know Act*, 9 B. U. J. SCI. & TECH. L. 156, 163 (2003).

<sup>127</sup> See *Id.* at 164.

<sup>128</sup> In California's recent vote for the mandatory labeling on GMOs, which is called "California Right to know Genetically Engineered Foods Act" (or Proposition 37), the initiative failed to pass by a narrow margin. See Alexandra Sifferlin, *California fails to pass genetically modified foods labeling initiative*, TIMES, Nov. 8, 2012, <http://www.cnn.com/2012/11/08/health/california-gm-foods/>

<sup>129</sup> See Miskiel, *supra* note 121, at 235.

<sup>130</sup> *International Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67 (2nd Cir. 1996).

<sup>131</sup> See Elaine Watson, *GMO labeling: How vulnerable is Proposition 37 to a legal challenge?*, FOOD (Oct. 24, 2012), <http://www.foodnavigator-usa.com/Regulation/GMO-labeling-How-vulnerable-is-Proposition-37-to-a-legal-challenge> (last visited Jan. 8, 2014); Miskiel, *supra* note 121, at 235.

far from the current international and environmental treaties, as well as the domestic demand in the US, seen in California, Connecticut, Maine, and Vermont.

#### **4. South Korea's approach to the labeling system**

South Korea enforces a mandatory labeling system within the area of GM crops and GM foods under the *LMO Act* enacted in 2008 and other preexisting laws. The Korean *LMO Act* regulates the labeling system on the stages of development, production, and import of GMOs. However, before the *LMO Act* was enforced, the labeling system had been already regulated by other laws, which consisted of two main parts that enforced mandatory labeling system.<sup>132</sup> One system, implemented by the Ministry for Food, Agriculture, Forestry and Fisheries (MFAFF) addresses the labeling system of GM crops. Korea Food & Drug Administration (KFDA) implements the other system and it deals with the labeling system of GM foods.<sup>133</sup>

The laws and its enforcement ordinances enacted by MFAFF and KFDA state the labeling requirements for GMOs, such as the person who is obligated to label products, the items that need to be labeled, and the labeling methods. First, according to the laws and implementing ordinances on GM crops under the MFAFF, the person who sells GM crops should label the presence of GM materials. The targeting items for GMO labeling are the items permitted to be eaten through the GMO risk assessment. The mandatory labeling items are beans, corns, bean sprouts, canola, cotton, and sugar beet, etc. Second, based on the laws

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<sup>132</sup> See SeJeong Yi, *Legal Issues on the LMO/GMO Labeling System*, 33-2 HWANGYEONGBEOP YEONGU [Environmental Law Journal] 35 (2011).

<sup>133</sup> See SUNGYONG PARK, CHANGKYUNG KANG & YONGSOO JEONG, HANGUKSOBIJAWON [KOREA CONSUMER AGENCY], A STUDY ON THE DEFINITION AND LABELING ISSUES OF GMO FOODS 51 (2010) [hereinafter KOREA CONSUMER AGENCY report].

and implementing ordinances about GM food or additives under the KFDA, the person who manufactures, processes, or sells GM food or additives should label GM materials, only if some GM DNA or foreign proteins still remain in it after manufacturing and processing the product. The GM food required to be labeled is the food that was made and processed by mainly GM crops such as beans, corns, and bean sprouts.

With regard to the labeling methods, South Korea requires detailed labeling of GM material in products that contain GMOs. The labeling method under the current South Korean system for the GM crops is one of the three ways: (1) “genetically modified (the name of crop),” (2) “containing GM crop,” and (3) “may contain GM crop.”<sup>134</sup> These methods for labeling are the same for all GM foods, which allow consumers to recognize the contents with ease.<sup>135</sup>

However, South Korea’s labeling system is not effective due to many exception clauses, which means the loopholes or exemptions in the mandatory labeling system have caused lots of conflicts regarding GMO regulation systems. In case of GM crops, regulated under the MFAFF, there exists a 3 percent threshold. When a crop includes less than 3 percent of GMO ingredients, the product does not need to have a GMO label. The rationale for this was due to the possibility of GM crops unintentionally mixing with non-GM crops. In order for the exemption to be valid, the sellers are needed to have a government certification or evidentiary documents to prove that their products have been managed separately from GM

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<sup>134</sup> See Park & Kim, *supra* note 10, at 100-101. Among these labeling methods, the “may contain” labeling method is problematic. Meanwhile, in South Korea, the legislation to accept the “GMO-free” labeling method has been issued, which indicates that the GM crop or GM food does not include GMOs. There is also a debate on this type of labeling. These labeling methods will be discussed in later section (Section III. B.3.).

<sup>135</sup> See *Id.* at 102-103.

products.<sup>136</sup>

Furthermore, the more problematic situation is found in the exception clauses in the case of GM food or food additives. If GM materials were not found in the final products, the products could be excluded from labeling because the mandatory labeling is required only when some GM DNA remains after manufacturing and processing. This is different from the EU's mandatory labeling system, which requires labeling regardless of whether GM DNA remains after processing. In reality, it is very rare to find GMO labeling in South Korea's markets due to this exception clause, even though South Korea enforces a mandatory labeling system. Other exception clauses include exclusion from labeling if the GM crops were not included in the five raw materials that were used the most, and foods or food additives that are manufactured or processed by raw materials containing less than 3 percent of the GM crops.<sup>137</sup>

In conclusion, South Korean *LMO Act*, relevant laws, and enforcement ordinances have established GMO labeling regulation in detail. However, the mandatory labeling system is ineffective and nominal because of the exception clauses, limiting the obligation scope to label in GM crops and GM foods. Therefore, it is necessary to close these loopholes for a more successful labeling system.

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<sup>136</sup> See Soojin Son, *A Study on the Improvement of the GMO labeling*, 21-2 HANYANGBEOPHAK [Hanyang Law Review] 19 (2010).

<sup>137</sup> See *Id.* at 23.

## 5. Summary

From looking at the US agency's passive attitude on GMO labeling regulation and EU's active and numerous enactments on GMO labeling system, the US has the most lenient GMO labeling system and the EU has the strictest and strongest GMO labeling system. Because the EU is strict with their labeling methods, the goals and ideas of the *Biosafety Protocol* are the most agreeable to the EU's labeling system. It seems that South Korea's GMO labeling system is similar to the EU's labeling system because both enforce mandatory labeling system. However, South Korea's GMO labeling system is located more in the middle of the US and EU's current labeling system due to the many exception clauses that exempt products from mandatory labeling duty. An exception clause barely exists in the EU's labeling system, and only has the exception of a threshold. Additionally, the number of the threshold (unavoidable adventitious presence) and the labeling methods of "may contain" or "GMO-free" exhibit South Korea's lenient system, compared to the EU. Consequently, the US does not adopt a mandatory system itself and the EU's GMO labeling system is almost too compact with very few exceptions. South Korea, on the other hand, is in the middle of the regulation spectrum, permitting many exceptions under the mandatory labeling system.

### **B. An ideal GMO labeling system and specific labeling methods with regard to consumers' right to know**

This paper's purpose is to search for the most reasonable international GMO labeling and liability system. The ideal labeling system should be able to deliver the GMO information relevant to the food that consumers will be purchasing and ultimately to protect

consumers' health. The first step toward this goal would be to decide on whether or not to generally adopt a mandatory labeling system. Then the next step would be to search for the efficient and specific labeling methods under the chosen system. Therefore, this section will discuss which system – mandatory or voluntary – is more efficient and what labeling measures are appropriate within that system. Additionally, the main discussion for both questions needs to focus on the concept of strengthening the consumers' right to know.

### **1. The necessity of the “Consumer’s Right to Know” reinforces the need for a labeling system**

While the other issues, such as GMO risk assessment or trade restrictive measures, are connected to the protection of humans and the environment, labeling (one of the GMO regulations) is unique in that it stresses the “consumers’ right to know.” As mentioned above, the scientific evidence to prove the complete safety or risk of GMOs is not certain under current circumstances. However, the important thing to consider in GMO labeling is that it does not decide how safe or how risky a GMO product is. The purpose of the GMO labeling system for foods containing GMOs is to let consumers know about the basic and fundamental information they eat and to let them choose the food products based on the information provided.<sup>138</sup>

Supporters for a mandatory GMO labeling system emphasize that consumers have a

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<sup>138</sup> Internationally, consumer policies have been established to ensure the basic human rights of consumers. The consumers’ right functions to improve the quality of life for the consumers and its rights include the right to be informed, the right to choose, the right to safety, the right to a healthy environment etc. *See* CONSUMERS INT’L-REG’L OFFICE FOR AFR. (CI-ROAF), BIOSAFETY LEGISLATION IN SELECTED COUNTRIES: A COMPARATIVE ANALYSIS 13 (2005).

right to know whether or not the food they eat have GM materials.<sup>139</sup> Generally, consumers show the tendency of “process preference” in the market.<sup>140</sup> The preference for process could effectively reflect consumer viewpoints and consumers would be a central force affecting the market under the process-based activities.<sup>141</sup> Additionally, within globalization, consumers demand for the flow of enhanced information and are not satisfied with the minimal product descriptions.<sup>142</sup> Therefore, legislators or policymakers should not undermine this consumers’ process preference and not presume that it is less valuable than the preference for product.<sup>143</sup> When it comes to the preference for process, the consumers’ right to know is essential and the GMO labeling system is needed. Meanwhile, given the consumers’ role in the market, the GMO labeling system is necessary. Because each consumer is asked to serve as the evaluative function in a private market behavior, consumers should be able to obtain information and the government should not conceal the information valuable to the consumers for this role.<sup>144</sup>

Additionally, both the proponents and opponents of GMOs would agree that the GMOs are consumed by human beings and should thus be helpful for human beings.<sup>145</sup> In this sense, consumers’ intent, whether to buy GM food, has to be respected and the information on whether the food contains GM material should be available for consumers.

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<sup>139</sup> See Federici, *supra* note 116, at 517.

<sup>140</sup> Douglas A. Kysar, *Preferences for Process: The Process/Product Distinction and the Regulation of Consumer Choice*, 118 HARV. L. REV. 525, 529 (2004).

<sup>141</sup> See *Id.* at 580 (explaining the distinction between *product-related information* and *process-related information*, and states that the *process preference* should be emphasized as a framework of GMO regulation policy).

<sup>142</sup> *Id.* at 641.

<sup>143</sup> *Id.* at 535.

<sup>144</sup> *Id.*

<sup>145</sup> See Christophe Chao-Hung Chen, *Labeling Genetically Modified Food-Comparative Law Studies from Consumer’s Perspective*, 1 NAT’L TAIWAN U. L. REV. 1, 27 (2006).

This will provide them with more choices, allowing them to make better decisions.<sup>146</sup>

## **2. Searching for an efficient labeling system: mandatory vs. voluntary**

The aim of the labeling system is to give consumers the basic and objective information under this scientific uncertainty. While the voluntary labeling system allows companies to choose whether or not to label GM products, the mandatory labeling system requires the labeling of GM products. Therefore, under the mandatory labeling system, it explicitly supports the consumers' right to know about whether the food they choose is a GM food or contains GM materials.<sup>147</sup> Proponents of the mandatory labeling system generally cast doubt on the safety of GMOs and point out the adverse effects of GMOs on human beings, including allergic reactions or toxic compound presence. They also state that it is up to the consumers to decide whether to purchase GM products based on the facts. Therefore, the consumer's right to know is best supported in the mandatory labeling system.

Additionally, a mandatory labeling system could be helpful to ensure the consumer's right to religion. Some people might object to GMOs because of their religion.<sup>148</sup> Therefore, under the mandatory labeling system, those who are concerned about GMO risks or are willing to reject GMOs for religious reasons, such as biblical laws, would be able to make those well-informed decisions.<sup>149</sup> Finally, the enforcement of the mandatory system is

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<sup>146</sup> *Id.*

<sup>147</sup> See Strauss, *supra* note 125, at 167 (stressing a stringent GMO labeling and monitoring system, and suggests a mandatory labeling system for the US as a novel regulatory approach in light of an increased consumer demand).

<sup>148</sup> See MEG BOSTROM & L.L.C. PUBLIC KNOWLEDGE, DIGESTING PUBLIC OPINION: A META-ANALYSIS OF ATTITUDES TOWARD FOOD, HEALTH AND FARMS 22 (2005).

<sup>149</sup> One example of biblical laws would be Deuteronomy 22:9 stating, "Do not plant two kinds of seed in your vineyard; if you do, not only the crops you plant but also the fruit of the vineyard will be defiled."



needed to follow the international community's application of the precautionary principle to the GMO regulations as well as the domestic demand. Even in the US, there is a strong need for mandatory labeling system as seen in a survey that shows 94 percent of consumers wanting to see all GM foods labeled on food products.<sup>150</sup>

In contrast, advocates for the voluntary labeling system contradict the mandatory labeling system with various reasons. First, supporters for the voluntary labeling system say that the special labeling for GMOs is not justified because the information may mislead consumers, rather than enlightening them.<sup>151</sup> They also worry that consumers have less knowledge on GMOs and would not interpret the information correctly, leading to consumer confusion. However, it is logical for the government to inform consumers what GMOs are, the safety and risks of GMOs, and how much GMOs are present in certain foods. This information provided by the government is fundamental knowledge, and every consumer has the right to know.<sup>152</sup>

Second, those who are in favor of a voluntary labeling system also argue that potential toxicity or new allergens, which are used as reasons for mandatory labeling proponents, should be directly addressed and be the main concern; not indicating GMOs. This means that what consumers want to know is not whether or not GMOs are present, but the toxicity or allergens present in the product. However, the other argument in regards to the

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See David Alan Nauheim, *Food Labeling and the Consumer's Right to Know: Give the People What They Want*, 4 LIBERTY U. L. REV. 97,103 (2009).

<sup>150</sup> See *Id.* at 108-109; Federici, *supra* note 116, at 530.

<sup>151</sup> See J. Howard Beales III, *Modification and Consumer Information: Modern Biotechnology and the Regulation of Information*, 55 FOOD & DRUG L.J. 105, 111 (2000) (mentioning that a mandatory labeling system for GMOs might mislead consumers rather than informing them of toxicity concerns). See also Burchett, *supra* note 114, at 200 (stating that EU's mandatory labeling system could mislead consumers due to the unavoidability of mixing of GM products with non-GM products).

<sup>152</sup> See Michael Hansen, *Genetically Engineered Food: Make Sure It's Safe and Label It*, in GENETICALLY MODIFIED ORGANISMS IN AGRICULTURE –ECONOMICS AND POLITICS 255 (Gerald C. Nelson ed., 2001).

direct indication of allergic action or toxic substances is not persuasive enough, for indicating the presence of GMOs in general will give this information anyway and the side effects of the supposed toxins and allergens have not been proven completely.

The final argument for the voluntary labeling system is that the mandatory system requires a lot of costs to enforce it.<sup>153</sup> They argue that the burden of the costs for the mandatory labeling system is unreasonable because those who do not care about GMOs should not have to take the burden of costs (even though the beneficiaries of the information are those who only care about GMOs). However, existing evidence states that the costs are not as high contrary to popular belief.<sup>154</sup>

Consequently, the mandatory labeling system is more efficient than the voluntary one, since it ensures the consumer's right to know with the consumer's right to choose and corresponds with the international and domestic demands.

### **3. The controversy surrounding specific labeling methods under a mandatory labeling system**

The language used in GMO labeling methods is a main concern for the mandatory labeling system. The language used, which is written on a certain GM products, plays a key role in GMO labeling systems. The specific labeling methods and the used languages are directly connected with what consumers will see and how this will affect the consumers' right to know. Some of the languages used in labeling have problems of confusing consumers rather than providing information about GMOs.

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<sup>153</sup> See Beales III, *supra* note 151, at 114-116; Burchett, *supra* note 114, at 190-197.

<sup>154</sup> See Strauss, *supra* note 125, at 192.

a. Problems of “may contain GMOs” labeling method

The direct indication of GMO content of either “Genetically Modified” or “contain GMOs” is used under the EU’s labeling system. On the other hand, the GMO labeling system of South Korea includes labeling items as: “Genetically Modified,” “contain GMOs,” and “may contain GMOs.”<sup>155</sup> Based on these current systems, it is necessary for more concrete indications in order to meet the consumers’ right to know and not to confuse consumers. Therefore, appropriate labeling methods should reflect the EU’s current system – “Genetically Modified” and “contain GMOs” labeling. The labeling of “may contain GMOs,” which means the possibility of containing GMOs, would be problematic from the perspective of protecting consumers. Also, it is unnecessary, considering the current high standard of technology to discern GMO presence. The “may contain GMOs” indication has the flaw that causes confusion and prevents consumers from choosing a product with the accurate GMO information.

b. Problems of “GMO-free” labeling methods which is negative and passive

The countries that require a mandatory GMO labeling system directly indicate and label the content of GMOs.<sup>156</sup> As mentioned in the domestic GMO labeling system, the EU and South Korea are countries that implement mandatory labeling systems and use a method of positive labeling, highlighting the presence of GMOs. However, the negative and passive labeling method of “GMO-free” is favored to some producers because it attracts consumers.<sup>157</sup> Even though there is no global consensus in accepting this type of labeling, some countries are permitting this “GMO-free” labeling under their GMO labeling

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<sup>155</sup> See KOREA CONSUMER AGENCY report, *supra* note 133, at 53-58.

<sup>156</sup> See Chen, *supra* note 145, at 22.

<sup>157</sup> See *Id.*

regulations.<sup>158</sup> The different attitudes on “GMO-free” labeling show the possibility for future debates between countries.

The “GMO-free” labeling method, however, has some problems. First, this negative and passive labeling has a risk in misleading consumers because it will make consumers think that other products might contain GM products, while the “GMO-free” labeled product is the only product without GMOs.<sup>159</sup> Second, enforcing this type of labeling method should guarantee that there is zero percent of GMOs in the food.<sup>160</sup> Additionally, even though the condition is guaranteed, this may still lead to consumer confusion. Therefore, it is reasonable that the permission or expansion of the “GMO-free” labeling methods should be limited, regardless of a voluntary or mandatory labeling system.

#### 4. Summary

The mandatory GMO labeling system seen in the EU and South Korea is more efficient than the voluntary labeling system in the US, since it increases the consumers’ opportunities to knowledgeably choose one product when deciding between a GM food and a non-GM food.<sup>161</sup> The preference for the mandatory labeling system is consistent with the

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<sup>158</sup> The US’ FDA, which enforces the voluntary labeling system, allowed “GMO-free” and the “USDA-Organic” labeling. *See* Federici, *supra* note 116, at 518. Additionally, in South Korea, the revision enactment in adding to the “GMO-free” method has been submitted in 2008. *See* KOREA CONSUMER AGENCY report, *supra* note 133, at 86. On the other hand, some countries, such as Swiss and Taiwan, prohibit “GMO-free” labeling.

<sup>159</sup> *See* WonSeog Park, *Analysis of Consistency of Korea’s LMO-Related Regulation with WTO TBT Agreement*, 12-4 CHUNGANGBEOPHAK [ChungAng Law Review] 301 (2010).

<sup>160</sup> *See* Chen, *supra* note 145, at 22.

<sup>161</sup> *See* Steve Keane, *Can a consumer’s Right to Know Survive the WTO?: The Case of Food Labeling*, 16 TRANSNAT’L L & CONTEMP. PROBS. 291, 329-332 (2006) (pointing out that the US government agencies and courts do not protect the consumer’s right to know completely, and also argue that the WTO should deal with non-trade issues, such as consumer’s right to know). *See also* Federici, *supra* note 116, at 555-556

consumers' current opinions and desires. Additionally, the EU's mandatory labeling system is more reasonable than South Korea's labeling system. Even though the regulation intensity and standards in South Korea is in the middle, South Korea's current GMO labeling system is not to be suggested as a compromise due to its many problems, such as excessive exceptions and confusion within its labeling methods. Finally, the EU's current labeling methods, which describes the GMO materials as accurately as possible, is the ideal GMO labeling system that will be the model for the new labeling regulation system, provided that the very strict threshold and traceability is generously adjusted.

### **C. Consistency of the EU's labeling system as an ideal GMO labeling regulation system under the WTO provisions**

Even though the EU's labeling system is the most reasonable, problems still exist with its system and need to be resolved regarding the EU's labeling system's consistency with the WTO provisions. The US, EU, and South Korea are members of the WTO, and the WTO related provisions (the SPS and TBT Agreement) are binding the three countries together. The issue of consistency is necessary to review due to the high possibility of future conflicts between the US and EU, as mentioned in the EC-Biotech case (Section II, E). In addition, the more consistent the EU's labeling system is to the current WTO provisions, the more likely the new proposed system (which is less strict than the EU's, but stricter than South Korea's) will be accepted on a global scale. In this section, the EU's consistency will be analyzed to disrupt the inconsistency claim given by the US. After explaining the key provisions of the

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(stating that it is necessary for the US to enforce a mandatory labeling system. It concludes that consumers would avoid GM foods in a short amount of time, but they would accept GM food in the long run with informed consumer choice).

SPS and TBT Agreement, the analysis of the EU labeling system's consistency with each relevant key provision of the SPS and TBT Agreement will be examined.

## **1. Current requirements and key provisions of the SPS and TBT Agreement**

Prior to the evaluating the consistency of the EU with the WTO, the applicable rules within the WTO provisions need to be determined. The rules that apply to this GMO labeling issue are the SPS Agreement and the TBT Agreement, which were concluded in the Uruguay Round.<sup>162</sup> The US could hypothetically try to challenge the two agreements and its consistency to the EU's labeling system. The GMO labeling requirement is more likely to be categorized as a technical measure, even though the labeling measure ultimately aims to protect human health and the environment as a SPS measure. In this paper, the two agreements will be addressed in regard to the EU's consistency with them.

### **a. The SPS Agreement**

The main focus of the SPS Agreement is the emphasis of the scientific evidence to justify the given measure.<sup>163</sup> When a WTO member's labeling regulations are evaluated as a sanitary or phytosanitary measures to protect human health, the regulatory measures should be based on scientific standards.<sup>164</sup> The emphasis on the scientific criteria of the SPS

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<sup>162</sup> See John Stephen Fredland, *Unlabel their Frankenstein Foods!: Evaluating a U.S. Challenge to the European Commission's Labeling Requirements for Food Products Containing Genetically-Modified Organisms*, 33 VAND. J. TRANSNAT'L L. 183, 197 (2000).

<sup>163</sup> In other words, the SPS Agreement purposes to "prevent domestic SPS measures from having unnecessary negative effects on international trade and being misused for protectionist purposes." See SIMONETTA ZARRILLI, UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT (UNCTAD), INTERNATIONAL TRADE IN GENETICALLY MODIFIED ORGANISMS AND MULTILATERAL NEGOTIATIONS – A NEW DILEMMA FOR DEVELOPING COUNTRIES 24 (2000).

<sup>164</sup> See *Id.* at 26.

Agreement is confirmed in many of the provisions, such as Article 2.2 and 5.7. The key provision will be whether or not the scientific evidence would be suggested sufficiently under the Article 2.2. The GMO labeling regulations should be necessary for a member country's sanitary goal, which is scientifically and sufficiently supported under Article 2.2.<sup>165</sup> Meanwhile, Article 5.7 regulates the situation when relevant scientific evidence to justify the SPS measure is insufficient, which includes the precautionary principle.<sup>166</sup> Therefore in a situation that a case is pertinent to scientific uncertainty, the main debate will be the application of Article 5.7, which permits interim measures within a reasonable period of time.

There are two other requirements besides the requirement relevant to science. Article 2.3 states that the labeling requirements as sanitary measures should not discriminate WTO members as arbitrary or unjustifiable, which is called the no discrimination duty.<sup>167</sup> Additionally, the harmonization clause under Article 3 states that the labeling measures should meet the international standards, such as the Codex Standards,<sup>168</sup> which is called harmonization duty. Therefore, the key provisions under the SPS could be summarized with three requirements: (1) scientific evidence requirement under Article 2.2 and 5.7, (2) no discrimination duty under Article 2.3, and (3) harmonization duty under Article 3.

#### b. The TBT Agreement

If the WTO Dispute Settlement Body considers the labeling requirements as a regulation of the product itself, the TBT Agreement will be reviewed.<sup>169</sup> Some believe that the labeling regulations should meet the TBT Agreement requirements because the labeling

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<sup>165</sup> See Fredland, *supra* note 162, at 202.

<sup>166</sup> See Winickoff et al., *supra* note 13, at 113; ZARRILLI, *supra* note 163, at 26.

<sup>167</sup> See Fredland, *supra* note 162, at 205.

<sup>168</sup> See *Id.* at 206.

<sup>169</sup> See ZARRILLI, *supra* note 163, at 26.

regulations are hard to be evaluated as sanitary measures by the definition in Annex A of the SPS Agreement.<sup>170</sup> Unlike the SPS Agreement, the TBT Agreement does not call for scientific evidence.<sup>171</sup> Instead, the TBT Agreement Article 2.2 provides a legitimate objective and that “technical regulations shall not be more trade-restrictive than necessary to fulfill a legitimate objective.” Article 2.1 also requires a WTO member not to discriminate domestic and imported products through the technical regulations.<sup>172</sup>

Therefore, the requirements of the TBT could be summarized with two elements: (1) the legitimate objective and the less trade-restrictive measure for accomplishing the objective under Article 2.2 and (2) the no discrimination duty under Article 2.1

## **2. The EU labeling system’s consistency with the SPS and TBT Agreement**

The labeling regulation of the EU, in which the mandatory labeling system and strict labeling methods are implemented, would be justified only if the SPS or TBT Agreement requirements are satisfied. Even though the EU’s strict labeling system is reasonable and ideal, it would be of no use if the EU’s labeling regulations were not consistent with the WTO rules. Additionally, the consistency should satisfy all the relevant provisions of the key provisions of the SPS and TBT Agreement because just a violation of one provision causes the violation of WTO rules.

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<sup>170</sup> See Michele M. Compton, *Applying World Trade Organization Rules to the Labeling of Genetically Modified Foods*, 15 PACE INT’L L. REV. 359, 398 (2003).

<sup>171</sup> See Fredland, *supra* note 162, at 209. See also Josling, *supra* note 56, at 122.

<sup>172</sup> See Arthur E. Appleton, *The Labeling of GMO Products Pursuant to International Trade Rules*, 8 N.Y.U. ENVTL. L. J. 566, 575 (2000).



a. Consistency with the SPS Agreement

In regards to first requirement, it might be difficult for the EU to prove the consistency with the SPS Article 2.2 directly. However, it is highly possible for the EU to assert the scientific uncertainty under the Article 5.7 and to prove the consistency with the SPS Agreement.<sup>173</sup> In other words, the EU's argument could be more persuasive when the Article 5.7 relevant to the precautionary principle applies to the GMO labeling issue, rather than the application of the Article 2.2. In addition to the necessity of labeling systems when scientifically uncertain, the EU could also show experimental results, which prove the real threats to humans and the environment as available scientific evidence.<sup>174</sup> According to the current evaluation on the GMO risks, the scientific evidences, which warn about the potential and negative effects of GMOs to humans and the environment, have been presented and the real threats are actually shown in some countries.

Additionally, in regards to the second requirement of no arbitrary or unjustifiable discrimination, the EU could assert that the same labeling regulations are applied to GMOs in the EU domestically.<sup>175</sup> Finally, the possible argument from the US with regard to the international standard is that the EU's labeling requirements are not based on the Codex standards because the Codex standards recommend a mandatory labeling system when GMOs are materially different from non-GMOs products.<sup>176</sup> However, EU can argue that their labeling system is consistent with the Codex standards on the ground that GM products are materially different from their natural products, which is a contrary interpretation by the

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<sup>173</sup> See Winickoff et al., *supra* note 13, at 116.

<sup>174</sup> See Sarah Lively, *The ABCs and NTBs of GMOs: The Great European Union –United states Trade Debate –Do European Restrictions on the Trade of Genetically Modified Organisms Violate International Trade Law?*, 23 NW. J. INT'L L. & BUS. 239, 254 (2002).

<sup>175</sup> See *Id.* at 255.

<sup>176</sup> See Fredland, *supra* note 162, at 215.

US.<sup>177</sup> A lot of countries are already moving towards the consensus for needing mandatory GMO labeling and specific labeling methods. The future international trend will continue to insist on strengthening the GMO labeling regulation systems, which will be enforced through international standards like the Codex guidelines.<sup>178</sup>

Consequently, considering all these supporting reasons by the EU, the EU's GMO labeling system satisfies the requirements of the SPS Agreement. It might be difficult for the EU to prove the consistency with Article 2.2 directly. However, it is highly possible for the EU to assert the scientific uncertainty under Article 5.7 and to prove the consistency with the SPS Agreement.

b. Consistency with the TBT Agreement

When looking at the TBT Agreement's consistency with the EU's labeling system on its own, the problem of whether the GMOs and non-GMOs are "like products or not" needs to be solved since the TBT Agreement is applied only on like products.<sup>179</sup> It is a controversial issue and has not been settled.<sup>180</sup> Some argue that GMOs and non-GMOs are "like products" when they are analyzed with four criteria: properties, nature and quality, end-uses, consumers' taste, and habits.<sup>181</sup> This opinion is favorable to the US because "like

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<sup>177</sup> See Lively, *supra* note 174, at 256.

<sup>178</sup> *Codex Alimentarius Commission* was established in 1963 to create food standards, principles, and guidelines under the Joint Food and Agriculture Organization (FAO)/World Health Organization (WHO) Food Standards Program. For many years, the *Codex Committee on Food Labeling* has been discussing a *Draft Proposed Guideline* for GMO labeling. An international standard for a mandatory GMO labeling system has been supported by many developed and developing countries, even though major GM crop producing countries, such as US, Canada, and Argentina, oppose the draft now. See Lim Li Ching, *International Standard Setting on Biosafety: An Introduction to Some Other International Agreements and Forums*, in BIOSAFETY FIRST -HOLISTIC APPROACHES TO RISK AND UNCERTAINTY IN GENETIC ENGINEERING AND GENETICALLY MODIFIED ORGANISMS, 444, 448 (Terje Traavik & Lim Li Ching eds., 2007).

<sup>179</sup> See ZARRILLI, *supra* note 163, at 27.

<sup>180</sup> See *Id.* at 30; Park, *supra* note 159, at 313.

<sup>181</sup> See Julian Wong, *Are Biotech Crops and Conventional Crops Like Products? An Analysis Under*

products” should be premised for the argument for labeling regulations’ inconsistency with the TBT Agreement. On the other hand, there exists a different prediction that GMOs and non-GMOs are not “like products” and the US might have a disadvantage in the “like products” debates.<sup>182</sup> This argument will be the EU’s best defense because the US will not be able to argue the inconsistency of the EU’s labeling regulations with the TBT Agreement.<sup>183</sup> This paper will presume that they are “like products” for the hypothetical discussion of consistency with the TBT Agreement.

In regards to the first requirement of the legitimate objective and less trade-restrictive measure, the EU could assert that the goal of the GMO labeling requirements is a legitimate desire for a uniform regulation due to the different implementation between European individual states. Also, the objective of protecting consumers would be a legitimate goal.<sup>184</sup> In response to this argument, the US could argue that the GMO labeling requirements of the EU are unnecessary obstacles to international trade.<sup>185</sup> However, the EU would have counter arguments against the US. First, the EU labeling requirements are necessary obstacles to trade because the EU’s labeling requirements could function to make the import of GMOs easy in the EU.<sup>186</sup> The other reason is that the labeling requirements could include technical measures that are significantly less restrictive than GMO imports bans. Therefore, the EU’s labeling requirements meet the requirements of Article 2.2 of the TBT Agreement.

Additionally, the labeling requirements of the EU satisfies the non-discrimination obligation under the TBT Agreement Article 2.1 since the methods of GMO labeling do not

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GATT, 2003 DUKE L. & TECH. REV. 27, 31(2003).

<sup>182</sup> See Compton, *supra* note 170, at 409.

<sup>183</sup> See *Id.*

<sup>184</sup> See Keane, *supra* note 161, at 330.

<sup>185</sup> See Fredland, *supra* note 162, at 217.

<sup>186</sup> See Lively, *supra* note 174, at 259.

require the disclosure of excessive information enough to discriminate the GM products of the US. Therefore, the EU's labeling system does not violate Article 2.1 of the TBT Agreement. In conclusion, the EU satisfies both TBT Agreement Article 2.2 and 2.1.

### **3. Summary**

GMO importing and exporting countries have very different labeling systems, which leads to conflicts. With regard to GMO trade, the potential conflict could occur when a country applies domestic GMO labeling requirements to internationally imported GM products.<sup>187</sup> The US could bring a claim to the WTO against the EU's GMO labeling regulations in the near future and the issue of the EU's consistency with the WTO provisions will be raised. According to the application and analysis of this paper, current EU's GMO labeling regulations do not violate the WTO provisions and is consistent with several provisions of the SPS Agreement and TBT Agreement.

Naturally and logically, South Korea's GMO labeling system will be consistent with WTO provisions because South Korea's system is less strict than the EU's labeling system. The scholars in South Korea state that the current labeling regulations of the South Korea are not problematic when it comes to the WTO provision consistency issue. However, there is room for more discussion on the GMO-free labeling with regards to South Korea, which remains a controversial issue.

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<sup>187</sup> See Appleton, *supra* note 172, at 570.

## **D. Possible future approaches for an ideal GMO labeling system regarding the current dissonance between countries**

### **1. Broad review of the three countries' labeling system**

As seen from each country's domestic laws and policies on GMO labeling, the US, EU, and South Korea have different views on GMO labeling. It is hard to conclude which labeling policy is the most reasonable, but it could be said that the EU's GMO labeling system is the most effective for protecting consumers' right to know.

Though there are lots of GM products in the US, the consumers' right to know is not effectively guaranteed due to the lack of mandatory and accurate labeling. Its voluntary labeling is neither effective without manufacturers' or corporations' active participation, nor consistent with the international flow, which is moving toward to mandatory labeling system. Additionally, the enforcement of voluntary "GMO-free" labeling is not recommended since it can confuse consumers.

In case of the EU, it satisfies consumers' right to know by providing information through strict GMO labeling. The EU enforces traceability to increase its effectiveness. The regulatory range of labeling is wide and specific, and the EU aims to apply the labeling system to almost all GMOs. The consumers' right to know and choose can be effectively guaranteed by enforcing and managing such a strong labeling system. However, since the EU's approval of GMOs is extremely limited, consumers have less of an opportunity to encounter GMOs.

Similar to the EU in the aspect of laws and policies, South Korea prepares the specific labeling measures and enforces a mandatory labeling system. However, its labeling

system is not properly working due to many exemptions and loopholes. It is necessary to make efforts to narrow down the range of exemptions in order to be similar to the EU's labeling system. Additionally, even in the case of GM food, it is advisable to determine the exemption after considering the importance of GM materials in the whole raw materials, rather than saying that it is not included in the top five ranking of material contents.

## **2. Possible future approaches for mediating future conflicts** (proposal for the GMO labeling system eliminating South Korea's drawbacks and weakening EU's strict policies)

The current GMO regulations are different in the three countries from its large frame to detailed matters. In order to reduce the resistance between nations, a phased approach is needed and it is important to seek for an interface that could be internationally acceptable. The labeling system is one of the preventive regulations based on the precautionary principle, and the GMO labeling regulation is realized as the most effective under the EU's system. Additionally, the EU's current labeling system could be considered as being in accord with WTO rules, such as the SPS and TBT Agreement.

However, too strict of a labeling system can be a cause for international conflicts. For example, there is a critique that the EU's standard on unintentional mixing of GMOs (a 0.9 percent threshold) is too excessive and much stricter than other countries, considering the characteristic of GMOs.<sup>188</sup> The threshold is critical because it is directly connected with the

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<sup>188</sup> See Burchett, *supra* note 114, at 200 (stating that "the EU's mandatory labeling framework is an illusory promise to the consumers by guaranteeing labeling thresholds that are difficult to enforce.").

obligation and exemption for labeling. As for the threshold in South Korea, the current regulation of 3 percent is sufficient, even though other countries that enforce mandatory labeling system use a 5 percent threshold. Therefore, the EU's GMO regulation and labeling policies should not progress towards a more rigid system.

### **3. Recommendations for South Korea's labeling system**

To meet the proposed ideal GMO labeling system, it is necessary for South Korea to correct some problems. There are hot debates on the expansion of GMO labeling in South Korea but it is more important to fix the current problems prior to the expansion of GMO labeling system. The excessive exceptions are a big problem in South Korea. It is necessary to reduce the exceptions and loopholes. The labeling ways of "may contain" or "GMO-free" do not help to improve the consumers' right to know and even confuses the consumers. Finally, South Korea has to pay more attention to the international trend for finding the global standards of GMO labeling and cooperate with other countries through clearing house continuously. South Korea needs to revise domestic laws in order to reduce excessive exceptions that is preventing the effectiveness of the laws and should be similar to the EU's labeling system. However, it is also required to maintain the current threshold because the EU is too strict on it.

## **IV. GMO Liability and Redress System**

### **A. Current international norms on GMO liability regime and the recent Liability and Redress Supplementary Protocol**

As seen in Section II, the *Biosafety Protocol* is the main global agreement that regulates the transboundary movement of GMOs. Its goals involve the safe treatment and management of GMOs under the precautionary principle. However, the *Biosafety Protocol* does not offer the substantial provisions necessary for liability and compensation, which would provide standards in case the damages resulted from GMOs. The GMO liability and redress is a very delicate issue and it is difficult to draw an agreement in the area of GMO liability and compensation. After highly debated discussions, parties did succeed in adopting the *Liability and Redress Supplementary Protocol* in 2010. Even though the adoption of this protocol itself is a positive outcome, there still remains a lot of room for improvement. A review and evaluation of this current *Liability and Redress Supplementary Protocol* will be a fundamental task, before looking for a reasonable GMO liability and compensation system.

#### **1. The CBD and Biosafety Protocol**

The *CBD* is an international environmental treaty that aims for protecting the biological diversity. *CBD*'s Article 14 mentions the necessity of reviewing the liability and redress issue on the damage of biodiversity. This article deals with broad concepts of biodiversity damage and does not directly focus on the specific harms caused by GMOs, even



though both of them have things in common.<sup>189</sup> Meanwhile, The *Biosafety Protocol*, which comes from the *CBD* and focuses on the transboundary movement of GMOs, states that the liability and redress issue for the damage results from the transboundary movement of GMOs in Article 27.<sup>190</sup> Article 27 of the *Biosafety Protocol* calls for the parties to establish procedures for addressing liability and redress caused by GMO transboundary movement and recommends that this task be completed within four years.<sup>191</sup> The *CBD* and *Biosafety Protocol* both state a general liability and redress system, but lack specific and substantial contents on damage caused by GMOs.

## **2. The adoption of the Liability and Redress Supplementary Protocol**

There have been many efforts in order to perform a duty under Article 27 of the *Biosafety Protocol*. The parties within the *Biosafety Protocol* have negotiated to make a harmonized liability and redress framework, preparing to protect human health and prevent environmental damage caused by GMOs.<sup>192</sup>

The first Conference of the Parties (COP) decided to establish the “Working Group” in order to address the liability and redress regime. Since then, the “Working Group” has met five times from 2005 to 2008.<sup>193</sup> Additionally, the fifth meeting of the “Working Group”

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<sup>189</sup> Katharine E. Kohm, *Shortcomings of the Cartagena Protocol: Resolving the Liability Loophole at an International Level*, 27 UCLA J. ENVTL. L. & POL’Y 145, 160 (2009).

<sup>190</sup> Elizabeth Duall, *A Liability and Redress Regime for Genetically Modified Organisms under the Cartagena Protocol*, 36 GEO. WASH. INT’L L. REV. 173, 174 (2004).

<sup>191</sup> *See Id.*

<sup>192</sup> *See* Anastasia Telesetsky, *Introductory Note to the Nagoya-KualaLumpur Supplementary Protocol on Liability and Redress*, 50 INT’L LEGAL MATERIALS 105, 105 (2011).

<sup>193</sup> *See* SeungHwan Choi, *Legal Issues in International Liability and Redress Rules regarding Living Modified Organisms*, 15-1 SEOUL GUKJEBEOP YEONGU [Seoul International Law Academy] 173 (2008).

suggested the formation of the “Friends of the Chair Group” to overcome any difficulty of an agreement. Only some of the main parties participate in negotiating, within this “Friends of the Chair Group” to mediate disagreements.<sup>194</sup> This effort shows the difficulty in coming to an agreement and concluding a protocol in the field of liability and redress systems. Until the fourth COP, parties failed to agree on the adoption because of conflicting debates between developing and developed countries.<sup>195</sup> However, in the fifth COP, the *Liability and Redress Supplementary Protocol* was adopted on October 15, 2010 in Nagoya, Japan.<sup>196</sup>

### 3. The main contents of the Liability and Redress Supplementary Protocol

The precautionary principle is the basic concept of the *Liability and Redress Supplementary Protocol*, similar to the *Biosafety Protocol*.<sup>197</sup> The main provision reflecting this principle is “response measures.” The preamble includes the provision that recognizes the necessity of a response measure in case there is a damage or sufficient likelihood of damage. The specific contents and requirements of the response measures are described in the *Liability and Redress Supplementary Protocol* Article 5. Under Article 5, the private operator is required to inform a competent authority immediately, evaluate the damage, and take appropriate response measures. A competent authority should then identify the operator,

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<sup>194</sup> See *Id.* at 175.

<sup>195</sup> See SeungHwan, Choi, *The EU's Liability System for Genetically Modified Organisms Damage and its Implications at the Negotiation to Adopt International Liability Rules*, 44-3 KYUNGHEEBEOPHAK [Kyunghae Law Review] 100 (2009).

<sup>196</sup> The parties of the *Liability and Redress Supplementary Protocol* are currently 24 countries. See UNITED NATIONS TREATY COLLECTIONS, [https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg\\_no=XXVII-8-c&chapter=27&lang=en](https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=XXVII-8-c&chapter=27&lang=en) (last visited Mar. 27, 2014).

<sup>197</sup> See SeungHwan Choi, *The main contents and evaluation of the Liability and Redress Supplementary Protocol*, 11-3 BAOSEIPEUTI JEONEOL [Biosafety Journal] 40 (2010).

evaluate the damage, and decide the response measure the operator should take. The domestic law implements these response measures. Known from this procedure, the response measures emphasize on the action by the State from the perspective of an administrative approach.<sup>198</sup>

The definition of the damage is particularly important because it is connected to a range of the application and compensation scope. The *Liability and Redress Supplementary Protocol* defines the damage as an “adverse effect on the conservation and sustainable use of biological diversity” and also considers the “risks to human health.” Therefore, the damage of the *Liability and Redress Supplementary Protocol* includes property damage, human health damage, and environmental harm, such as biodiversity damage, but it does not just include the possibility of damage.<sup>199</sup>

The *Liability and Redress Supplementary Protocol* provides a civil liability system, which enables to make a claim against the operator. Article 2(2) (c) states the operator is any person who controls GMOs directly or indirectly and exemplifies operators, such as a permit holder, developer, producer, notifier, exporter, importer, carrier, etc. Two exemptions to the operator’s liability described in Article 6 are: Act of God (or *force majeure*) and Act of war (or civil unrest). However, it is possible for a contracting party to provide other exemptions under Article 6.

The noteworthy feature of the *Liability and Redress Supplementary Protocol* is that it remains in many important areas, such as the areas that should be resolved by domestic law, including the response measures and exemptions. The specific areas that should be resolved by domestic law include causation, time limits, and presence of financial stability. First,

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<sup>198</sup> *See Id.*

<sup>199</sup> *See* SeungPil Choi, *Compensation for Damages as the Additional Protocol of Biosafety Protocol*, 34-1 HWANGYEONGBEOP YEONGU [Environmental Law Journal] 140 (2011).

domestic laws should establish the factors of causation. A causal link between the damage and GMOs is the main element that is required in a lawsuit, regardless of fault-based and strict liability standards. Second, contracting parties could set time limits for a lawsuit. Third, the presence of financial security, such as a liability fund, depends on the domestic legislation.

#### **4. Evaluation of the Liability and Redress Supplementary Protocol**

The adoption of the *Liability and Redress Supplementary Protocol* does include some positive aspects. First, the *Liability and Redress Supplementary Protocol* makes countries predict liability standards in GMO related lawsuits as an international unified norm, which leads to increased GMO trades.<sup>200</sup> In addition, from the perspective of the exporting country, the state or companies relevant to GMO development will try to follow the rules of the *Liability and Redress Supplementary Protocol*. The importing party will become friendly to the GMO import due to the guaranteed liability system.<sup>201</sup> Both parties involved in GMO trades could feel more comfortable with the predictable liability agreements and it will help increase GMO trades.

However, critics say that the *Liability and Redress Supplementary Protocol* failed to set forth an international liability and redress standard by assigning the role to the domestic country's legislation.<sup>202</sup> In other words, despite the necessity of substantive international standards, the *Liability and Redress Supplementary Protocol* does not provide the uniformity

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<sup>200</sup> See Choi, *supra* note 193, at 172.

<sup>201</sup> See JaeHyup Lee, *Liability and Compensation for LMOs Accidents*, 39-2 KYUNGHEEBEOPHAK [Kyunghee Law Review] 178 (2004).

<sup>202</sup> See Telesetsky, *supra* note 192, at 106.

in the field of GMO liability and redress by just providing a process-oriented regime.<sup>203</sup>

Consequently, the different domestic laws might cause conflicts and forum shopping problems in the international civil actions.<sup>204</sup> This result of failure in adopting international civil liability guidelines is contrasted to the other international protocols, which have established strict liability standards in oil pollution liability or nuclear accident liability, etc.<sup>205</sup>

## **B. Possible framework on a new GMO liability and redress regime**

A reasonable international model for GMO liability is necessary due to the lack of efficiency in the currently concluded protocol. In order to form a well-functioning GMO liability regime, the broad framework should be well equipped. Also, the standards on specific judicial issues that might be raised in a real lawsuit should be established. The latter of each litigation topic will be addressed in Section C. This section will look into the possible wide approach of state responsibility, civil liability and state liability. Then, an effort to create a reasonable approach for enhancing the effectiveness of the GMO liability and compensation will be discussed. In order to analyze each system, it is necessary to examine the existing environmental liability protocols, which could be a role model for GMO liability regime. Additionally, this section will examine the need for a fund, along with the wide approach on the liability framework, which will improve the effectiveness of the liability system. Also, a fund system from existing environmental liability protocols could provide this problem with

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<sup>203</sup> See Duall, *supra* note 190, at 190.

<sup>204</sup> See Choi, *supra* note 197, at 45.

<sup>205</sup> See Telesetsky, *supra* note 192, at 105.

some insight to the discussion of needing a fund.

# **1. Characteristics of other current liability regimes in the international environmental laws**

The necessity of an international liability regime has been recognized in the international environmental laws system, as shown in the Declaration 22 of *1972 Stockholm Declaration*.<sup>206</sup> Especially, the risk and harm of nuclear accidents or oil contamination accidents, where the environmental damage occurs outside its territory, increased the need for an international liability regime. The international environmental treaties in the area of a nuclear and oil pollution have addressed the liability issue and established a civil liability regime, not a state liability.<sup>207</sup> *The Basel Convention on the Control of Transboundary Movement of Hazardous Wastes and Their Disposal* (Basel Convention) also adopted a civil liability regime as a supplementary protocol titled: *the Basel Protocol on Liability and Compensation Resulting from the Transboundary Movement of Hazardous Wastes and Their Disposal* (Basel Liability Protocol).

In short, states have established a liability and compensation regime based on international environmental treaties. The established liability regime (in the area of nuclear, oil pollution to transboundary movements of hazardous wastes) features a civil liability regime.

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<sup>206</sup> See Lee, *supra* note 201, at 175.

<sup>207</sup> See PETER MALANCZUK, AKEHURST'S MODERN INTRODUCTION TO INTERNATIONAL LAW 244 (7th ed. 1997). See also Kohm, *supra* note 189, at 163.

## 2. Reasonable options for the GMO liability and redress regime: state responsibility, civil liability and state liability

Many broad approaches to the liability regime have been discussed in many treaties, as well as in the *Liability and Redress Supplementary Protocol*. The possible options are state responsibility, civil liability, and state liability.<sup>208</sup> Each of them has its own function and one option does not necessarily exclude the other option. This section explains the definition and role of each option and then looks at what the most reasonable option is for the GMO liability and redress regime.

### a. State Responsibility

State responsibility could naturally apply as an established principle in international law. In international laws, a state is responsible when there is a commitment of a breach, an internationally wrongful act by violating codified international laws or rules of customary international laws.<sup>209</sup> A state is obligated not to cause transboundary environmental harms and this principle could be accepted as a customary international environmental law.<sup>210</sup> Therefore, if a state violates the obligation under the *Biosafety Protocol* or fails to exercise due diligence to prohibit individuals from causing harms, the state is responsible for its conduct and should compensate for the damage occurred to other states.<sup>211</sup> State responsibility is still meaningful in case the protocol is insufficient for certain situations, even

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<sup>208</sup> See SeungHwan Choi, *Discussion on Liability and Redress (Biosafety Protocol Article 27)*, 6-2 BAIJOSEIPEUTI JEONEOL [Biosafety Journal] 43 (2005).

<sup>209</sup> See MALANCZUK, *supra* note 207, at 254.

<sup>210</sup> GURDIAL SINGH NIJAR, INST. FOR AGRIC. AND TRADE POLICY, DEVELOPING A LIABILITY AND REDRESS REGIME UNDER THE CARTAGENA PROTOCOL ON BIOSAFETY –FOR DAMAGE RESULTING FROM THE TRANSBOUNDARY MOVEMENT OF GENETICALLY MODIFIED ORGANISMS 14 (2000), *available at* [http://www.iatp.org/files/Developing\\_a\\_Liability\\_and\\_Redress\\_Regime\\_unde.pdf](http://www.iatp.org/files/Developing_a_Liability_and_Redress_Regime_unde.pdf)

<sup>211</sup> *Id.* at 15.

though a liability regime set forth a civil liability regime.<sup>212</sup> As an example, the *Basel Liability Protocol* acknowledges the need for state responsibility and provides that this protocol has no influence in the state responsibility in Article 16.<sup>213</sup> Likewise, the *Liability and Redress Supplementary Protocol* also states that this supplementary protocol does not affect the state responsibility in Article 11.

However, the state responsibility role is not critical in the environmental liability regime due to uncertainties.<sup>214</sup> The state responsibility has its own applicable area and the role of the state in liability and damage compensation internationally should be emphasized because it encourages states to follow the global environmental norms.

b. Civil Liability as the general liability system

When the damage occurred is against humans and the environment, it is reasonable for the person who controls the hazardous source and causes the damage to assume a liability for it. Primarily, the liability could be tort liability caused by transboundary pollution by private actors. Many predecessors, which adopt a civil liability, show that the civil liability regime is the most persuasive approach in international liability and compensation for damages caused by an operator.<sup>215</sup> This civil liability, which holds a private operator to account, is consistent with the “polluter pays” principle established in the EU.<sup>216</sup> The “polluter pays” principle means that the burden to be liable for damage should be placed on

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<sup>212</sup> *Id.* at 1-2.

<sup>213</sup> *Id.* at 51.

<sup>214</sup> See Jutta Brunnee, *Of Sense and Sensibility: Reflections on International Liability Regimes as Tools for Environmental Protection*, 53 INT’L & COMP. L. Q. 351, 354 (2004).

<sup>215</sup> For a detailed status of civil liability treaties, see Noah Sachs, *Beyond the Liability Wall: Strengthening Tort Remedies in International Environmental Law*, 55 UCLA L. Rev. 837, 854-857 (2008).

<sup>216</sup> See Choi, *supra* note 195, at 112.



the private operator who uses and deals with GMOs directly.<sup>217</sup> Under the civil liability regime, it is possible that there exist numerous operators related to the human and environmental damage accidents. The specific problems with regard to liable parties and the relationship between the private operators involved will be examined in Section C.

Civil liability system can directly provide victims with monetary remedy. Additionally, this system can force biotechnology firms related to GMO development to be careful of the harms that might be caused by GMOs. However, civil liability system is also not complete and shows weakness when private actors, who are liable, are insolvent.

### c. State liability and Residual State Liability

State liability means that a state is obliged to be liable for the harmful consequences of hazardous activities, even though the state did not violate international laws. For example, there is no violation in operating a nuclear plant close to a border, but the state could be liable for the radioactive contamination damage to a neighboring injured state.<sup>218</sup> When it comes to discussing state liability, two approaches are possible: primary state liability and residual state liability.

The residual state liability emphasizes the role of state liability as a subsidiary liability system to the civil liability regime. A state liability system is necessary, but the “residual state liability” system is more recommendable than the primary state liability. It is because the key role of state liability is to support the civil liability system, and the civil liability system is the most effective in forming a direct remedy to the injured, which reflects

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<sup>217</sup> A. Bryan Endres, “GMO:” *Genetically Modified Organism or Gigantic Monetary Obligation? The Liability Schemes for GMO Damage in the United States and the European Union*, 22 LOY. L.A. INT’L & COMP. L. REV. 453, 499 (2000).

<sup>218</sup> See MALANCZUK, *supra* note 207, at 254.

the polluter pays principle.

Opponents to the state liability say that the intervention by a state is not reasonable when the private party is responsible for the damage. However, state liability could support a civil liability system and also function well when the operator is not identified, as well as deemed insolvent. It is very burdensome and difficult for operators to compensate for all the damage occurred unless the operator can afford to redress as a conglomerate.<sup>219</sup> Additionally, the fact that states are involved in the transboundary movement of GMOs by developing, exporting, and approving them, is a key reason for them to be involved and justifies the need for state liability. This will ultimately lead to a complete and thorough liability system.

d. Conclusion for a reasonable GMO liability and redress regime

In order to follow the current environmental liability regime and at the same time enhance the effectiveness of the liability system, it is reasonable to adopt the civil liability system as a main compensation scheme and supplement it with the state liability system. The adoption of civil liability regime does not exclude the other options, and it would be strengthened by the supplement of a state liability regime. Other countries have suggested this solution to possibly fill the gaps in the civil liability regime.<sup>220</sup> Additionally, the civil liability system supported by a state liability system is helpful in establishing a thorough GMO liability system. Even though there are only a few real cases, the thorough liability system is necessary since the scope of damage caused by GMOs might be more serious than expected. There are several loopholes if only a civil liability system was used. For example, there is a possibility of establishing a sham company to avoid the liability. It is also possible

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<sup>219</sup> See Choi, *supra* note 199, at 141.

<sup>220</sup> See Duall, *supra* note 190, at 197 (proposing the combination regime as an optimal regime for the GMO liability subject. This article states that the combination of not only a civil and subsidiary state liability, but also a fault and strict liability system to be recommendable).

for a legitimate business being incapable of compensating the damage. Therefore, a state liability system supporting a civil liability system will help close the loopholes (e.g., sham company or insolvency problems) that the civil liability system used alone might cause.

Therefore, a subsidiary liability by state is necessary for effective judicial remedies for the injured party, which will help call both an operator's and a state's attention.<sup>221</sup>

### **3. Need for an international fund for damage compensation caused by GMOs**

#### **a. Insurance as a financial security method and its evaluation**

The first possible system that could be utilized as a full and adequate compensation system is insurance. The Nuclear treaties and *Basel Liability Protocol* require operators to take out insurance in case the harms occur in their nuclear facilities.<sup>222</sup> The oil pollution treaties also require operators to maintain insurance, and the ship operators should obtain insurance according to the oil tonnage or size of the ship.<sup>223</sup> The insurance system could be successful only when the accurate damage quantification is guaranteed, but it is not easy to quantify the environmental damage.<sup>224</sup> Therefore, the insurance system is not a good option in regards to GMOs. Finally, in the current GMO liability regime, the international fund by the biotechnology industry is more recommendable than the insurance system (even though the *Liability and Redress Supplementary Protocol* just provides the right to retain financial

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<sup>221</sup> See *Id.* at 198.

<sup>222</sup> See Kohm, *supra* note 189, at 168.

<sup>223</sup> See *Id.* at 170.

<sup>224</sup> See Lee, *supra* note 201, at 191.

security by parties).<sup>225</sup>

b. The function of a fund

The international fund for damage can be a method to compensate the injured party when the responsible party is insolvent or is not found.<sup>226</sup> The scope of the damage and the amount of compensation could be much larger than expected, especially in environmental damage, which makes the person liable for damage insolvent. When there is a limit within the relevant treaty and the liability exceeds the limit, a fund could cover the damage and give compensation to the injured party.<sup>227</sup> Another possibility of insolvency is that a shell biotechnology company might be established by a multilateral biotechnology enterprise.<sup>228</sup>

In preparation for these cases, the fund will be the way to guarantee adequate compensation. Therefore, it is necessary, regardless of whether the liability system is fault or strict liability.<sup>229</sup>

c. The function of an international fund

An efficient and full compensation should be ensured in the international level, as well as the domestic level. Compensation will consider the possibility of a wide range of damages and involve a considerable sum of money. Each country would establish its own financial security system reflecting their own financial circumstances, since the *Liability and Redress Supplementary Protocol* provides the right to provide for financial security according

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<sup>225</sup> See NUJAR, *supra* note 210, at 67.

<sup>226</sup> See Kohm, *supra* note 189, at 179. See also GREENPEACE, GREENPEACE INTERNATIONAL BACKGROUNDER FOR THE 4TH BIOSAFETY LIABILITY AND REDRESS MEETING 10 (2007) [hereinafter GREENPEACE report], available at <http://www.greenpeace.org/international/en/publications/reports/2007-backgrounder-biosafety-liability-redress/>

<sup>227</sup> See NUJAR, *supra* note 210, at 67.

<sup>228</sup> See GREENPEACE report, *supra* note 226, at 11.

<sup>229</sup> See *Id.*

to their domestic law. Therefore, a global fund is needed for the efficiency of the liability system, besides the different domestic financial security methods.

Opponents of a fund system in the international environmental laws say that it might weaken the damage deterrent. However, it could be contradicted by the fact that GMO trade and transboundary movement occurs frequently in current circumstances and deterrence is meaningless, especially in case of GMOs.<sup>230</sup>

- d. A specific issue for the fund enforcement (by whom the international fund be raised)

The fund is set up by relevant industry parties, such as multinational biotechnology businesses that produce GM products and other operators. For example, the oil industry pays contributions to the fund under the *Oil Pollution Fund Convention*.<sup>231</sup> It is necessary to adopt an international fund in the GMO liability system, like the fund in the *Oil Pollution Fund Convention*. It is important to note that this fund-raising by relevant operators is consistent with the polluter pays principle.

### **C. Specific judicial issues under international civil liability lawsuits when considering a new Liability and Redress Supplementary Protocol**

The recently concluded *Liability and Redress Supplementary Protocol* has failed to create standards or guidelines on each potential judicial issue, but the need for international consent still remains. This section aims to propose a reasonable GMO liability regime as an

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<sup>230</sup> See Kohm, *supra* note 189, at 172.

<sup>231</sup> See NUJAR, *supra* note 210, at 67.

international model in addressing each liability issue. This section will look into the hypothetical situations related to the GMO liability lawsuit that could become issues between the different countries. Additionally, reflecting the GMO characteristics and fundamental principles that the *Biosafety Protocol* and *Liability and Redress Supplementary Protocol* are based on will also help create an effective GMO liability system.

## **1. Hypothetical situations to consider for possible GMO liability lawsuits**

The hypothetical situations show that a variety of damages caused by different kinds of GMOs might occur and these damages need to be compensated for. Predicting some of the possible situations is meaningful in order to address legal issues and to find better solutions in the circumstance that there is an actual international lawsuit related to GMO damages. Hypothetical situations in this section are between two or more countries since the *Liability and Redress Supplementary Protocol* aims to cover the liability issues caused by the transboundary movement of GMOs (like *Biosafety Protocol*).

The first hypothetical situation that could occur involves GMO damage to the biodiversity due to intentional introduction into the environment. After exporting the GMOs made for intentional introduction into the environment, the GMOs could cause damage to the biodiversity, creating super weeds due to the genetic superiority and destroying the habitats of other native organisms.<sup>232</sup> Additionally, this could involve the possibility of GMOs, meant for intentional introduction, being introduced into the environment by accidentally flowing out to a third country during the movement from the exporting country to the importing

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<sup>232</sup> See Kohm, *supra* note 189, at 151. See also Tana N. Vollendorf, *Genetically Modified Organisms: Someone is in the Kitchen with DNA Who is Responsible When Someone Gets Burned?*, 21 MISS. C. L. REV. 43, 45 (2001).

country. This eventually leads to environmental damage in the third country.<sup>233</sup> Second, the environmental damage accidents could happen during the transboundary movement of GMOs for contained use. The environmental harm, such as air, water and soil pollution, might occur in the destination country, and also occur in a third country by an unintentional leak accident, similar to the first case.<sup>234</sup> Third, the human health damages could arise in the trade of GM products and GMOs intended for direct use as food or feed. Therefore, the GM food or feed imported could cause allergen reactions to the importing countries' consumers who eat it.<sup>235</sup>

Seen from these hypothetical situations, the damages include potential environmental harms, as well as becoming harmful to human beings. Also, the damages caused by GMOs are presumed to happen in all types of GMOs, even in the country that the GMO movement is not intended for originally. These hypothetical situations show that the GMO liability regime is necessary to cover all types of GMOs and GMO damages in order to give an effective and sufficient relief of damage to an injured party or consumer of GMOs.

## **2. The uniqueness of GMO liability regime and principles to consider**

For a more effective and efficient liability system, the uniqueness of GMO liability (including the uniqueness of GMOs) and key relevant principles have to be reviewed. As the multilateral environmental treaties that address other areas (e.g., nuclear, oil and hazardous wastes) have come up with their own liability regimes to reflect the characteristics of each

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<sup>233</sup> See Lee, *supra* note 201, at 180-181.

<sup>234</sup> See *Id.* at 182.

<sup>235</sup> See Kohm, *supra* note 189, at 153; Lee, *supra* note 201, at 183.

respective field, the GMO liability system should most definitely include the uniqueness of GMOs, due to its scientific uncertainty. Another consideration in creating a GMO liability system should be based on the fundamental principles that have already been established in the international environmental law and liability law.

a. Characteristics of GMO liability

As seen in Section II and Section III, there exists scientific uncertainty on whether the GMOs are a risk to human health and the environment. Under this scientific uncertainty, the GMOs have been developed by multinational conglomerates (such as Monsanto) and have shown a dramatic expansion in planting and exporting.<sup>236</sup> The GMO liability states that if the damage caused by GMOs is realized, the damage may be serious and irreversible, which actually make the evaluation and compensation for the damages difficult.<sup>237</sup> Another feature of GMO liability is that the GMO risk is latent and it may take a very long time for the risk to be realized after the transboundary movement. This uniqueness could make proving the causal link difficult.<sup>238</sup> In the process of transboundary movement of GMOs, many parties could be involved as operators, including manufacturers, exporters and importers. Therefore, in determining who is liable for the damage, the channeling of the liability should be considered.<sup>239</sup>

The litigious issues of GMO liability, which will be discussed, should reflect the current uniqueness of GMOs, such as a lack in scientific certainty, irreversible damage, long period effects, and multiple operators. The system reflecting these GMO characteristics could

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<sup>236</sup> See Vollendorf, *supra* note 232, at 43-44.

<sup>237</sup> See Duall, *supra* note 190, at 193.

<sup>238</sup> See Kohm, *supra* note 189, at 165.

<sup>239</sup> See Duall, *supra* note 190, at 198.



make the GMO liability system more efficient and compromising.

b. Use of “polluter pays” principle and precautionary principle

In order to create reasonable international GMO liability standards, these standards have to be based on fundamental principles of the existing international environmental principles. The “polluter pays” principle means the polluter who controls the pollution source should take the burden of paying compensation. The *Rio Declarations on Environment and Development* (Principle 16) provides this principle. Some say that the strict liability system is more consistent with the “polluter pays” principle than fault liability.<sup>240</sup> However, the “polluter pays” principle does not have a direct and logical connection with a strict liability system. This is due to the function of this principle placing the financial burden on relevant operators, not the state. Therefore, any standard of liability between fault and strict liability types could be chosen under the “polluter pays” principle.

Additionally, the use of precautionary principle should be well reflected in the *Liability and Redress Supplementary Protocol*, as well as the *Biosafety Protocol* liability system. This principle acknowledges the need for environmental protection measures in case of a potential serious risk. Under the precautionary principle, the expansion of the application scope in each issue (a mitigation of litigation requirements) would be persuasive. Therefore, many international or national agreements based on strict liability could be understood based on how much more it reflects the precautionary principle in the field of a liability regime.<sup>241</sup>

For a sound and reasonable GMO liability system in the future, the system should accommodate the fundamental principles such as the “polluter pays” principle and the

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<sup>240</sup> See GREENPEACE report, *supra* note 226, at 9.

<sup>241</sup> See Kohm, *supra* note 189, at 155.

precautionary principle. It should also consider the nature of GMO characteristics and uniqueness.

### **3. Key judicial issues possible for current systems and reasonable future standards in GMO liability lawsuits**

This section will address the main issues on what the definitions of damage, party, standard of liability, and exemptions are. The solutions for each hypothetical judicial issue should improve the effectiveness of remedy for injured parties, and at the same time consider the current scientific uncertainty of GMO risks. Since establishing reasonable standards in each issue requires striking a balance, it is a difficult but necessary task to set up substantial international standards in the area of GMO liability.

#### **a. Definition of the damage caused by GMOs**

The *Liability and Redress Supplementary Protocol* broadly defines what the damage is in this protocol. According to the report suggested during the discussions, the damage in this protocol includes environmental damage (including air, water, and soil pollutions), biodiversity damage (genetic variability and ecosystem destruction), harms to humans (health or property damage), and response measures cost.<sup>242</sup> Among the harms associated with GMOs, the environmental harm is especially difficult to address since a causal link is hard to prove and the scope of damage is hard to define. However, it is important and noteworthy to discuss these issues and create a potential solution.<sup>243</sup>

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<sup>242</sup> See Kohm, *supra* note 189, at 177; Choi, *supra* note 208, at 41.

<sup>243</sup> See Christopher Rodgers, *Implementing the Community Environmental Liability Directive*:

The GMOs included under the *Biosafety Protocol* are GMOs intended for direct use of food, feed, or processing, GMOs for contained use, and GMOs for intentional introduction into the environment. This definition means that the damage by processed GM products is excluded from the damage scope. This definition might make the liability and redress system very ineffective. From the perspective of the precautionary principle, it is reasonable for the *Liability and Redress Supplementary Protocol* to embrace many kinds of damage. Therefore, for the efficient damage relief, it is necessary to cover the damage caused by GM products because the GMO damage could occur mainly by GM products.

Meanwhile, the evaluation of the damage is also important since it determines the amount of compensation necessary. For this evaluation, the GMO risk assessment should be utilized. The risk assessment could be helpful in assessing all the possible damages arising from GMOs by giving more accurate information on GMOs.

b. Parties (Plaintiff and Defendant)

The GMO liability should cover as many involved parties as possible. As explained in the characteristic of GMO liability lawsuits, many parties could be involved in GMO lawsuits. The parties, such as a producer, an exporting state, a notifier, a carrier, an importer, and an importing state, could be liable as an “operator” under the *Liability and Redress Supplementary Protocol*.<sup>244</sup> There were many controversies between countries on the defendant issue (the question on who was liable for the damage occurred). There was also a suggestion that the liability could be channeled to any one person.<sup>245</sup> However, each person

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*Genetically Modified Organisms and the Problem of Unknown Risk, in* THE REGULATION OF GENETICALLY MODIFIED ORGANISMS: COMPARATIVE APPROACHES 199-201 (Luc Bodiguel & Michael Cardwell eds., 2010) (stating that a public liability mechanism could play a role in compensating for biodiversity damage).

<sup>244</sup> See NUJAR, *supra* note 210, at 60-62.

<sup>245</sup> See Choi, *supra* note 208, at 66.

involved participates in the transboundary movement of GMOs with its own obligations. Therefore, it is reasonable that all those who are attributed to the GMO damage occurrence should be liable, depending on their fault. Also, the idea that all persons who is liable must compensate for the damage as operators is very consistent with the “polluter pays” principle.<sup>246</sup> Many of the parties mentioned above, who contribute to the damage occurring caused by GMOs and control the damage, should be liable and compensate for the damage under the “polluter pays” principle.

Similar to the defendant issue, there is also a need for the expansion of the scope in the plaintiff issue. The *Basel Liability Protocol* does not provide this, but it is interpreted as any person suffering damage can raise a GMO liability lawsuit.<sup>247</sup> Even though the *Liability and Redress Supplementary Protocol* does not specify the possible plaintiff, it is possible to presume that any person who suffers damage could be a plaintiff, including individuals and entities. Furthermore, especially in the field of environmental damage claims, there is a question on whether the environmental organization, which is not injured directly, could file a liability lawsuit.<sup>248</sup> The need for the expansion of standing to sue is recognized in the GMO liability lawsuit that is associated with environmental damage. Embracing as many parties as a plaintiff, including environmental organizations could be helpful for an efficient and strong liability system.

c. Standard of liability (fault liability vs. strict liability)

Establishing the standard of liability is the most essential and difficult part in order to contribute to the decision of a liability lawsuit outcome. As mentioned before, the standard of

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<sup>246</sup> See GREENPEACE report, *supra* note 226, at 10.

<sup>247</sup> See NUJAR, *supra* note 210, at 62.

<sup>248</sup> See Choi, *supra* note 208, at 44-45.

liability also should meet the need for reflecting characteristics of GMOs and the fundamental liability principle. Furthermore, it should follow the basic principle of a civil liability system and at the same time, efficiently protect the injured party using the precautionary principle.

The *Liability and Redress Supplementary Protocol* has adopted a civil liability system, and the basic principle under a civil liability system is that a plaintiff should prove the defendant's fault in order to claim damages. On the contrary to this fault-based liability, the strict liability has been developed in some multilateral treaties addressing ultra-hazardous activity, such as nuclear or oil pollution. The strict liability standard applies to abnormally dangerous activities that create catastrophic damages, even though the possibility of this happening is low.<sup>249</sup> This strict liability system removes obstacles of fault liability system, such as the burden of proof imposed to a plaintiff, and makes the defendant liable without fault.<sup>250</sup>

However, it is presently hard to determine whether a GMO transboundary movement is an abnormally dangerous activity. As mentioned several times above, the risk of GMOs in current circumstances is scientifically uncertain. Even though it is true that the evidence and experiments to prove the potential harms of GMOs have been increasing, it does not necessarily demand a strict liability system. Additionally, under the international environmental law, a strict liability system could not be considered as a customary law until now.<sup>251</sup> In order to mitigate the conflict of opinions between the developed countries' fault liability assertion and the developing countries' strict liability assertion, a theory of

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<sup>249</sup> See NUJAR, *supra* note 210, at 64.

<sup>250</sup> See Ramon Ojeda Mestre, *Consultative Opinion on Liability of Public and Private Actors for Genetic Contamination of Non-GM Crops*, 7 ENVTL. L. REV. 253, 271 (2005).

<sup>251</sup> See NUJAR, *supra* note 210, at 18.

compromise has been suggested called the “mitigated strict liability.”<sup>252</sup> Meanwhile, the *Basel Liability Protocol* provides a combination of strict and fault liability, which applies a fault liability standard in case violations occur, and applies a strict liability standard in case of no violations. However, both of these examples are not reasonable since the first mitigated strict liability does not set clear criteria for the standard of liability and the *Basel Liability Protocol* is excessively favorable for a plaintiff.

Finally, it is reasonable to follow a fault-based standard, which is a fundamental principle of a civil liability system. As a next step, some ways to lighten a plaintiff’s burden of proof should be designed for balancing and complementing a plaintiff’s adverse condition in the area of biotechnology techniques, such as GMOs.

#### d. Exemptions and Time Limit

In a liability lawsuit, exemptions and time limit are necessary to be dealt with carefully because they are directly connected with the outcome of the lawsuit. As the exemptions to release a defendant from the obligation of being liable for the damage, the *Liability Redress Supplementary Protocol* provides the Act of God and Act of war defenses. However, besides these exemptions, a state of the art defense could be discussed as a possible defense, a protest of inevitability under the modern technology. Even though a party could provide this state of the art defense by its domestic laws, the *Gene Technology Act* explicitly excludes the state of the art defense.<sup>253</sup> Like Germany, it is reasonable not to include this defense in a GMO liability lawsuit due to the possibility of a state of the art defense letting a defendant escape from the liability in many cases. In order to protect the injured party and

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<sup>252</sup> See Kohm, *supra* note 189, at 176, 179 (arguing that a mitigated-strict liability is reasonable as a GMO liability regime).

<sup>253</sup> See KyungWoon Jeon, *The liability system of the Gene Technology Act in Germany*, 9-4 BAIOSPEUTI JEONEOL [Biosafety Journal] 81 (2008).

compensate adequately for the damages caused by GMOs under the precautionary principle, the exemption needs to be minimized.

The time line issue, which is a period decision for a plaintiff to file a lawsuit against a defendant, is important because it could affect the possibility of litigation itself. Since it could take a while to realize the damages caused by GMOs, it is necessary to set longer time limits in GMO liability lawsuits, considering the uniqueness of GMOs.<sup>254</sup> Even though the EU has set a time limit of thirty years, critics suggest that thirty years may be too short.

#### **4. Summary**

Like the GMO labeling system, it is necessary to compromise and balance the GMO liability system and compensation regime. It is too early to adopt a strict liability system under the current scientific uncertainty evidence on GMO risks. In a civil liability framework, the balanced liability system should be the choice of fault-based liability while mitigating a plaintiff's burden of proof, making up for the weakness of the plaintiff. This solution will be consistent with the "polluter pays" principle. Additionally, the specific standards of each judicial issue are also required to reflect the "polluter pays" principle and precautionary principle. In resolving the possible legal issues regarding the definition of damage, litigation parties, and time limits, it is necessary to extend the scope toward a more effective compensation for the damages caused by GMOs using the precautionary principle. It would be best not to extend the exemptions in the same context.

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<sup>254</sup> See Rodgers, *supra* note 243, at 217.

#### **D. Possibility for a new GMO liability legislation based on existing domestic laws**

The specific problems discussed in the previous section are controversial since the existing *Liability and Redress Supplementary Protocol* does not substantially and efficiently regulate current international liability issues by asking each country to regulate according to its own law.<sup>255</sup> Therefore, it is necessary to discuss the existing domestic liability laws. Additionally, establishing reasonable and agreeable standards within domestic laws will be helpful to create international agreements in regards to each issue listed in Section C. Countries could use these existing laws to deal with international GMO liability or make new legislations that are specific in its liability and compensation laws only for GMOs. If the current domestic laws are reasonable and reflect the principles suggested in Section C, there would be no conflict. However, if they do not reflect the suggested principles, the countries should consider a revision or new law for GMO liability. Since each country's circumstance is different in the US, EU, and South Korea, this section will first review each country's existing laws and evaluate them in order to create a comprehensive GMO liability law. Finally this section will express the need for harmonization in a GMO liability system between countries in order to overcome the problems that different domestic laws may cause.

##### **1. Current circumstances regarding GMO liability system in the US, EU and South Korea**

There are two options within GMO liability. Some specifically deal with the liability caused by GMOs and some do not recognize GMOs as being special and different from other

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<sup>255</sup> See Duall, *supra* note 190, at 190.



environmental harms. Within the attitudes of specially dealing with GMO liability, some countries regulate GMO liability with general liability legislations, such as environmental liability laws. On the other hand, some countries deal with GMO liability with specific domestic laws, focusing on the GMO liability and compensation itself. The US, EU, and South Korea have different circumstances in addressing the GMO liability and compensation.

a. US approach

As seen in the GMO labeling system, the US does not have a comprehensive law for GMO regulations and also does not have a liability law for the damage caused by GMOs.<sup>256</sup> Even though there is an effort to enact a law dealing with biotechnology in some states, these laws do not include provisions on the liability issue.<sup>257</sup> Therefore, the GMO related lawsuit in the US relies on existing common law tort remedies, which are negligence, strict liability, and nuisance.<sup>258</sup> However, these tort law remedies are insufficient within each of the categories.

First, the existence of duty to exercise reasonable care is required for the negligence claim.<sup>259</sup> For example, a farmer has an obligation to comply with governmental authorization and the farmer who fails to follow the duty could be sued.<sup>260</sup> Second, the strict liability system is also accepted and the Restatement of Torts is to list the factors in order to determine the abnormally dangerous activities.<sup>261</sup> Specifically, biotechnology manufacturers of biotech

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<sup>256</sup> See Endres, *supra* note 217, at 481.

<sup>257</sup> See Vollendorf, *supra* note 232, at 48.

<sup>258</sup> See Endres, *supra* note 217, at 482.

<sup>259</sup> See Margaret Rosso Grossman, *Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State Measures, and Liability in Tort*, in *THE REGULATION OF GENETICALLY MODIFIED ORGANISMS: COMPARATIVE APPROACHES* 328 (Luc Bodiguel & Michael Cardwell eds., 2010).

<sup>260</sup> See Vollendorf, *supra* note 232, at 50.

<sup>261</sup> See *Id.* at 52.

product could be strictly liable under the strict products liability system.<sup>262</sup> The strict products liability system is significant enough to force manufacturers to prevent them from producing a potentially hazardous organism.<sup>263</sup> Third, there are two kinds of nuisance: private nuisance and public nuisance.<sup>264</sup> A farmer who grows traditional or organic crops could sue against a neighboring farmer who grows GM crops on the basis of private nuisance.<sup>265</sup> The StarLink case<sup>266</sup> and Monsanto case<sup>267</sup> are the representative public nuisance cases.<sup>268</sup>

In the US, the torts law is applied to the GMO liability lawsuits as an existing common law due to the lack of laws that only address GMO liability issues.<sup>269</sup> Therefore the current GMO liability system might not be strong enough, given that the existing laws do not sufficiently cover the GMO liability and redress issues.

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<sup>262</sup> See Brady L. Montalbano, *It's not easy Being Green – Holding Manufacturers of Genetically Modified Bentgrass Liable under Strict Products Liability*, 14 PENN ST. ENVTL. L. REV. 111, 119 (2005-2006).

<sup>263</sup> See *Id.* at 130. See also Faure & Wibisana, *supra* note 99, at 24.

<sup>264</sup> A *private nuisance* is an unreasonable interference of another's interest in the private use and enjoyment of land, such as physical invasion of land, loud noises, or noxious smoke. On the other hand, a *public nuisance* is an unreasonable interference with a public right, such as public health, public safety, or public comfort. See Grossman, *supra* note 259, at 324-325.

<sup>265</sup> See Margaret Rosso Grossman, *Genetically Modified Crops in the United States: Federal Regulation and State Tort Liability*, 5 ENVTL. L. REV. 86, 102 (2003).

<sup>266</sup> *Marvin Kramer v. Aventis CropScience USA Holding, Inc.*, 212 F.Supp.2d 828 (2002). In this case of *In re StarLink Corn Products Liability Litigation*, there was a class action by maize farmers against Aventis CropScience and StarLink. The plaintiff argued the public nuisance, as one of tort causes of action, that StarLink's failed to comply with EPA requirements and it led to contamination of the US maize supply. The court concluded the defendant should offer remedies for the damages. See Grossman, *supra* note 259, at 331-333. For an evaluation of this case, see Linda Beebe, *In re StarLink Corn: The Link Between Genetically Damaged Crops and an Inadequate Regulatory Framework for Biotechnology*, 28 WM. & MARY ENVTL. L. & POL'Y REV. 511 (2004).

<sup>267</sup> *Sample v. Monsanto Co.*, 283 F.Supp.2d 1088 (2003).

<sup>268</sup> See Grossman, *supra* note 265, at 101.

<sup>269</sup> See Grossman, *supra* note 259, at 330.

b. EU's approach

The EU has tried to come up with a liability regime that focuses on environmental liability for a long time, and the *Directive 2004/35* on environmental liability was recently adopted to satisfy this regime.<sup>270</sup> The *Directive 2004/35* is based on the “polluter pays” principle, placing the burden on the polluter who causes the damage to compensate for the damage.<sup>271</sup> Under the *Directive 2004/35*, operators are responsible for the imminent threat of damage, as well as the damage already occurred. This strongly reflects the precautionary principle.<sup>272</sup> However, this Directive is not complete and does not cover all the damages caused by GMOs since the Directive deals with only environmental damage and excludes traditional damage (i.e., loss of life, human body and property damage). Also, the Directive does not impose the right to claim for compensation on private parties.<sup>273</sup> In addition to the *Directive 2004/35*, the *Directive 85/374*, which deals with products liability system in the EU, could apply to the GMO liability lawsuits. It provides strict liability and has been revised to include primary agricultural products.<sup>274</sup> However, the *Directive 85/374* covers only economic injury or property damage.<sup>275</sup> Seen from these Directives, the EU does not have a Directive for GMO liability and the existing Directives cover only a limited area.

Meanwhile, even though the EU does not have a Directive that specifically deals with the GMO liability and compensation, Germany has a domestic law to regulate liability

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<sup>270</sup> See Ludwig Kramer, *Discussions on Directive 2004/35 Concerning Environmental Liability*, 2 J. EUR. ENVTL. & PLAN. L. 250 (2005).

<sup>271</sup> See *Id.* at 253.

<sup>272</sup> See *Id.* at 259.

<sup>273</sup> The public liability mechanism could cover the disadvantage of tort law remedies by linking compensation to the restoration of damaged natural habitats, and not just focusing on the economic damages. See Rodgers, *supra* note 243, at 201.

<sup>274</sup> See Endres, *supra* note 217, at 462.

<sup>275</sup> See *Id.* at 503.

for the damage caused by genetic engineering. It is called the *Gene Technology Act*, which could be applied to the damage caused by GMOs. The *Gene Technology Act* provides a strict liability system and excludes the state of the art defense, as mentioned in Section C (d).<sup>276</sup> Furthermore, this act considers the fact that having information on GMOs is not equivalent between a plaintiff and defendant, and provides a provision to cover this problem by imposing the right to ask information to a plaintiff.<sup>277</sup>

The EU has a lot of laws relevant to the GMO liability and redress system showing their effort to set up a reasonable GMO liability system in the EU, including member state's improved law (e.g., *Gene Technology Act* by Germany). However, all the laws are insufficient due to the limited areas covered in its liability and compensation systems regarding GMO damage.

#### c. South Korea's approach

The *LMO Act*, enacted in South Korea as an implementation of the *Biosafety Protocol*, does not have a provision relevant to liability and compensation. After the adoption of the *Liability and Redress Supplementary Protocol*, there is currently a discussion in South Korea. Some say that the existing *Civil Act*, *Product Liability Act*, and *Framework Act on Environmental Policy* are enough, while some argue that a new legislation for GMO liability is necessary.

First, the torts law under the *Civil Act* adopts a fault liability principle, which requires an injured party to prove the opposite party's fault and causal link. Therefore torts law is not

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<sup>276</sup> See Jan-Erik Burchardi, *The Proposed Amendments to the German Biotechnology Law: Progress or Setback for Biotechnology in Germany?*, 4 J. EUR. ENVTL. & PLAN. L. 449, 452 (2007); Charles Lawson, *Information Asymmetry, GMOs and Strict Liability under the Gene Technology Act 2000 (CTH)*, 5 QUEENSLAND U. TECH. L. & JUST. J. 123 (2005).

<sup>277</sup> See Lawson, *supra* note 276, at 124.

enough for the relief of the injured party.<sup>278</sup> Specifically, it is very hard for the victims to prove the fault and causal link because most information regarding the GMOs was given to large companies and is very limited to the consumer victim.<sup>279</sup> Second, the *Product Liability Act* provides a strict liability, but there is a limit for the application of the GMO liability case. Under the *Product Liability Act*, the primary agricultural products are excluded from the scope of this law, unlike the revised *Directive 85/374* of the EU.<sup>280</sup> Even though the GM crops are included in the scope of this law, the relief of a victim is also difficult since the state of the art defense is not excluded (unlike the *Gene Technology Act* of Germany). Finally, the *Framework Act on Environmental Policy* provides a strict liability system but it only covers the environmental damage occurred in a place of business.<sup>281</sup> Therefore, it is doubtful that the existing laws will apply to the GMO liability cases, and it is also difficult to fully cover the damages.<sup>282</sup>

Like the US and EU, South Korea has not established a GMO liability system with special legislation, and only uses the existing domestic laws. These existing laws have a limitation in how it applies to the GMO liability lawsuits, which leads to a discussion on a new and specific legislation about GMO liability and redress.

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<sup>278</sup> See Lee, *supra* note 201, at 198.

<sup>279</sup> See JaeHo Bang & SangHyuk Moon, *Limitation of Civil Liability and Legal Norms of Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety*, 7-1 SAENGYEONGYUNRI YEONGU [Bioethics Policy Studies] 53 (2013).

<sup>280</sup> See *Id.* at 39.

<sup>281</sup> See *Id.* at 47.

<sup>282</sup> See Choi, *supra* note 199, at 146.

## **2. The limits of existing laws and need for a new legislation on GMO liability system**

The US, EU, and South Korea do not have a comprehensive liability system that only applies to GMO liability and compensation. It is necessary to form a GMO liability and redress system with a new legislation for all three countries. First, existing domestic laws have limitations. Since the torts laws are based on just fault liability, without a supplementary tool to lighten the burden of proof, it is hard for a plaintiff to get relief from the damage caused by GMOs.<sup>283</sup> Additionally, there is a concern that the existing laws, providing a strict liability, would not apply to the GMO liability lawsuits due to the failure to meet the requirements. Another reason for needing a new domestic legislation is that without a comprehensive liability law for GMOs, the uniqueness of GMOs cannot be well reflected in the liability lawsuits resulting from GMO damages. In other words, the existing laws are not sufficient to cover the characteristics of GMO damages, the complexity of parties, and the potential long-term effects of GMOs.<sup>284</sup>

The existing laws of the US, EU, and South Korea have a problem covering all aspects of GMOs since each law is too narrow and the GMO characteristics are not fully defined. Therefore, a new legislation for a GMO liability and redress is needed for an efficient relief of damages caused by GMOs. The new legislation will also be helpful in giving an easy and comprehensive understanding on how each country prepares its GMO

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<sup>283</sup> Gurdial Singh Nijar, *Liability and Redress for Damage Arising from Genetically Modified Organisms: Law and Policy Options for Developing Countries*, in BIOSAFETY FIRST –HOLISTIC APPROACHES TO RISK AND UNCERTAINTY IN GENETIC ENGINEERING AND GENETICALLY MODIFIED ORGANISMS 488 (Terje Traavik & Lim Li Ching eds., 2007) (stating that “The burden of proving that the damage from a GMO is the result of the breach of the defendant’s duty may be onerous, given the complex and technical nature of the subject.”).

<sup>284</sup> See MICHAEL MIGUS, CANADIAN INST. FOR ENVTL. LAW AND POLICY, GMO STATUTORY LIABILITY REGIMES: AN INTERNATIONAL REVIEW 3 (2004).

liability system.

### **3. Global harmonization in making a liability system within each country**

Along with needing an independent law for a GMO liability system in each country, the uniformity of domestic law in the countries is required. Meanwhile, since the *Liability and Redress Supplementary Protocol* allows for a party to implement a stricter legislation, it is possible and encouraging that some states have an advanced type of law, as seen Germany's *Gene Technology Act*. Even though a more advanced and stricter domestic law like EU is ideal nationally, it is not always reasonable internationally. A much stricter domestic law would cause a dissonance with other countries on international level, and it creates a possible international conflicts. Additionally, the difference and big gap might cause other problems of international jurisdiction and forum shopping.<sup>285</sup> A successful GMO liability regime could be guaranteed if a balance within and between each liability issue exists. This will lead to greater participation among the countries and in embracing the GMO exporting countries.<sup>286</sup> Therefore, the adoption of fault-based liability is deemed to be reasonable as a basic principle under a civil liability regime. This new potential regime should also be accompanied by the mitigation of the burden of proof to create a balance between the parties in a lawsuit.

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<sup>285</sup> See Duall, *supra* note 190, at 192. Forum shopping means that a plaintiff decides one court preferable to him rather than another possibly available court. International forum shopping occurs when the decision is related to the courts between two or more countries' courts due to transnational disputes. See Cristopher A. Whytock, *The Evolving Forum Shopping System*, 96 CORNELL L. REV. 481, 485-486 (2010). The forum shopping on an international level is problematic because it leads to an unfair conclusion to at least one of the relevant countries.

<sup>286</sup> See Duall, *supra* note 190, at 191.

When the countries reach an agreement toward a reasonable liability system, the unified domestic laws of each country will help resolve the forum shopping problem and also affect international laws positively by making it easier for a future international agreement in the area of GMO liability. In addition, it will be also helpful to follow good examples from other countries by sharing information through the Clearing House (under the *Biosafety Protocol*).<sup>287</sup> The right to information disclosure claim of the *Gene Technology Act* in Germany could also be an example of a recommendable system. By cooperating with each other for agreeable international and domestic standards, the future international GMO liability lawsuits could be solved with less conflict.

## **V. Conclusion**

The varying attitudes on GMOs among the US, EU, and South Korea creates international trade conflicts. It should be mediated by establishing reasonable labeling and liability system focused on preventing potential GMO risks. Even though the system, which emphasizes the precautionary principle, is ideal, the balanced and compromised approach that accepts the opposite arguments is needed due to totally different attitudes and interests among the countries. Addressing the GMO issues and finding a reasonable GMO labeling and liability regulation is very complex and difficult since the conflicts are between developed and developing countries and also amongst the developed countries (e.g., the US and EU). However, if a reasonable standard in GMO regulation is established, it would be valuable in other fields (e.g., science, technology, and bioethics) dealing with other relevant issues

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<sup>287</sup> See *Id.* at 196.



regarding legal regulations.<sup>288</sup>

First, the GMO labeling is a very controversial global issue, especially in the countries involved in GMO exports and imports. The interest conflicts between countries arguing for a mandatory labeling and voluntary labeling system will likely cause international trade disputes. In addition, consumers are less informed and confused by GMOs, which leads to vague fear of GMOs. Therefore, specific and clearly defined rules for GMO labeling regulations are needed to follow the principle of the consumer's right to know. The important thing about consumer's right to know within the GMO labeling regulation is that the discussion on whether to label GMOs and how to label GMOs is relevant to the consumers' right to know and irrelevant to the decision as to whether the GMO are safe or harmful.

This paper is based on the idea that the GMO labeling system needs to be strict and specific, because having a labeling regulation is the most lenient and fundamental regulation under the scientific uncertainty principle. The ideal labeling system should be provided for the purpose of delivering the basic information of GMOs to consumers with the methods of reducing consumer's confusion. For these reasons, the mandatory GMO labeling system is more efficient than the voluntary labeling system in enforcing "consumer's right to know." The EU's current labeling system that requires the labeling for all the GM foods without exceptions is the best way to describe the GMO materials in the most precise and accurate manner, and to best satisfy the consumers' demand for GMO information. Additionally, the EU's mandatory labeling system is consistent with the WTO rules of the SPS and TBT Agreement. However, completely doing it EU's say is too strict. Therefore, a new system that incorporates EU's current mandatory system and eliminates South Korea's drawbacks is

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<sup>288</sup> For the discussions on the ethics of genetic engineering, see *generally* MICHAEL J. SANDAL, THE CASE AGAINST PERFECTION (2007).

needed. For example, too strong of a threshold in the EU is not recommendable, and the problematic labeling methods causing confusion, such as “GMO-free” labeling should not be allowed even though South Korea permits this labeling method.

Consequently, having an efficient labeling system will be great in that it will ensure the fundamental regulation under the scientific uncertainty by giving accurate facts and information on GMOs, satisfying consumer’s demand. Additionally, it will help solve the other issue of GMO liability by making it easy to find the source of damage when the liability disputes arise.

Next, the GMO liability system also needs clearly defined standards since current *Liability and Redress Supplementary Protocol* under the *Biosafety Protocol* is not efficient. With the mandatory labeling system, an efficient GMO liability system will reduce concerns about GMO risks and GMO damages. Additionally, in the circumstances of inevitable growth and trade of GMOs, the negotiated international standard under the GMO liability will give benefits to both parties of exporting and importing countries by facilitating GMO trades based on the predictable agreement for the exporting party and guaranteeing sufficient damage relief for the importing party.

The GMO liability system and derived specific standards should protect the party injured by GMOs in the direction of compensating the damage fully and efficiently using the precautionary principle. Mitigating the burden of proof is also important when considering the imbalance between a plaintiff damaged by GMOs and a defendant having a lot of information on GMO technology. At the same time, the GMO liability system should not infringe the basic rules of a liability lawsuit. Synthesizing these directions for the GMO liability system on an international level, the most reasonable option for the international GMO liability and redress system is to adopt a civil liability system supported by state

liability and international funds. The standard of liability should be a fault-based liability under the civil liability system, not a strict liability, since the strict liability standard is a little hard to be accepted in current circumstances. Meanwhile, domestically, even though there are many laws in the US, EU, and South Korea, it is not enough to cover all the possible damages caused by GMOs to the human and the environment. Therefore, newly enacted laws for the GMO liability and redress regime are required in all three countries of the US, the EU, and South Korea because of the loopholes in the international laws and the insufficiency of the domestic laws. The new and comprehensive law regarding GMO damage, liability and compensation should embrace the uniqueness of GMOs.

In conclusion, having an efficient liability system and setting up agreeable standards will ensure solving future international lawsuits without difficulty. If each country tries to make a new liability system domestically toward the ideal international standards, the GMO liability system could be strengthened and avoid the forum shopping problem.

The US, EU, and South Korea should make an effort for the proposed labeling and liability system, recognizing different situations to face with. As a leader of biotechnology, including GMOs, the US's consideration of joining the *CBD* and *Biosafety Protocol* will be the first step for the effective GMO regulation.<sup>289</sup> The EU has shown that the strictness in both GMO labeling system and liability system and the EU's Directives and Regulations regarding GMOs give a lesson as how the precautionary perspective works in regards to the GMO risks. However, it is necessary for the EU to keep pace with other countries by continuously sharing information and being compromising with other countries. Finally, South Korea has to try to make a balanced argument in international negotiations on GMO

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<sup>289</sup> For the necessity and benefits of the US participation in the *CBD*, see William J. Snape III, *Joining the Convention on Biological Diversity: A Legal and Scientific Overview of Why the United States Must Wake Up*, 10 SUSTAINABLE DEV. L. & POL'Y 6, 13 (2010).

regulations. The current GMO labeling regulation that accepts too many labeling exceptions needs to be revised in order to improve the effectiveness of the GMO labeling system. Additionally, simplifying the current administrative agencies will be helpful for the improving the regulation process. In regards to a GMO liability system, the new and comprehensive liability enactment for the GMOs is recommendable, rather than just including some provisions to the current *LMO Act*.

In order to continue the growth of GMOs and enjoy the benefits from the GMOs, it should go hand in hand with a legal infrastructure. To enhance the effectiveness of the legal system, the effort to make this legal system practical for countries is necessary. Furthermore, if the international cooperation and monitoring systems are added, it will help advance the GMO regulations.<sup>290</sup> In this sense, it is reasonable for South Korea's *LMO Act* to add a new provision in 2012 that requires a concerned minister of an administrative agency to examine, monitor, and publicize the GMO environmental effects.

The purpose of this paper is to provide a legal analysis of the GMO labeling and liability system, and it does not utilize the scientific, economic and social approach. However, a manifold approach and finding connections between these other fields of research are necessary to solve GMO issues. The socioeconomic analysis would be a valuable alternative approach. The discussion on how to deal with the socioeconomics damage and including it into the compensation for the damages should especially be taken into consideration. Additionally, the possibility of GMOs as an alternative of bioenergy and derived legal matters from this could be an area for future research.

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<sup>290</sup> For more information on environmental monitoring strategies and monitoring program design templates, see FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS [FAO], GENETICALLY MODIFIED ORGANISMS IN CROP PRODUCTION AND THEIR EFFECTS ON THE ENVIRONMENT: METHODOLOGIES FOR MONITORING AND THE WAY AHEAD 6-21 (Kakoli Ghosh & Paul C. Jepson eds., 2005).

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