

## SAFETY ASSESSMENT AND LIABILITY REGULATIONS IN THE CONTEXT OF GENETICALLY MODIFIED FOOD IN THE BRICS COUNTRIES

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DOI: 10.21684/2412-2343-2017-5-1-27-55

*International trade of food products is expected to increase rapidly with the widespread introduction of genetically modified (GM) food. There will be greater participation of developing countries based on investment as well as research and development. Investment in research and development and commercial production of GM crops is high in Asia, particularly in India and China, but also in Latin American countries, such as Brazil, and on the African continent, especially in South Africa. Despite the merits, the introduction of GM foods in the world market has continued to raise public concerns touching upon health, legal, social, ethical and environmental issues. Especially, the issue of contamination is considered a significant threat at many stages of development of GM food. Transboundary aspects and certain aspects of the components of the food safety system such as safety assessment, liability and redress are still not completely addressed. The present study is the systematic review of the extent of the development of legislation and institutional mechanisms in relation to safety assessment and liability mechanisms for regulating the emerging GM foods in the developing countries of BRICS. Additionally, the comparison of the components of national food safety systems of Brazil, Russia, India, China and South Africa reveals differences in policy and regulation in relation to GM food.*

*Keywords: food policy; regulation; genetically modified food; developing countries; BRICS; food safety assessment; liability; transboundary; comparative analysis.*

**Recommended citation:** Shanmugam Kabaleeswaran Balashanmugam, *Safety Assessment and Liability Regulations in the Context of Genetically Modified Food in the BRICS Countries*, 5(1) BRICS Law Journal 27–55 (2018).

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## Introduction

The significant role of GM technology in agriculture and export performance is quite impressive in developing countries which surpassed the developed world in 2011.<sup>1</sup> Among the developing countries, the commercial production of GM crops is high in Asia, particularly in India and China, but also in some Latin American countries, such as Brazil, as well as in a few African countries, especially South Africa. As of 2015, the total population of BRICS (Brazil, Russia, India, China and South Africa) was over 3.6 billion people (considered to be half of the world population).<sup>2</sup> Brazil is the second largest producer of GM next to the United States.

The public concerns about genetically modified (GM) food and crops are not new. In fact, the potential health concerns of GM foods were advanced as early as 1994, simultaneously with the inception of GM food.<sup>3</sup> To some extent, these concerns

<sup>1</sup> James Clive, *20<sup>th</sup> Anniversary (1996 to 2015) of the Global Commercialization of Biotech Crops and Biotech Crop Highlights in 2015*, ISAAA Brief No. 51, ISAAA: Ithaca, NY (2015). In 2015, 54% or 97.1 million hectares of land were cultivated with GM crops by 18 million small and resource-poor farmers from 20 developing countries.

<sup>2</sup> Population Ranking Table, Population Ranking from the World Bank (Feb. 20, 2018), available at <http://data.worldbank.org/data-catalog/Population-ranking-table>; The World Factbook, Central Intelligence Agency, United States of America (Feb. 20, 2018), available at <https://www.cia.gov/library/publications/the-world-factbook/rankorder/2119rank.html>.

<sup>3</sup> Irvin E. Liener, *Implications of Anti-Nutritional Components in Soybean Foods*, 34(1) Critical Reviews in Food Science and Nutrition 31 (1994).

became a reality in 1999, when GM foods were commercialised.<sup>4</sup> Also, reports have claimed that in experiments rats fed with GM foods have developed cancerous cell growth in the intestinal tract.<sup>5</sup> In addition to this, scientists have reportedly identified possible allergens which might cause adverse health effects after the introduction of GM food into the food supply chain.<sup>6</sup> The health apprehensions in respect of GM food were aggravated with the news of the first human death caused by ingestion of GM food, which was reported at a Madrid hospital in Spain in 2015. Medical examiners and forensic experts in that case identified the cause of death as the consumption of tomatoes containing fish-related genes and antibiotic resistant genes which had prevented the development of white blood corpuscles (WBC).

There are also instances showing that safety concerns over GM food were realised for potential impact and risk(s) in several other countries. For example, a study conducted by the Department of Food Science and Technology, University of Nebraska, identified that the gene developed from Brazil nuts when introduced to GM soybean causes allergies in human beings.<sup>7</sup> Also, there are instances showing that there is a high chance of contamination of conventional food with GM food in the process of trade. The GM contamination register, a documentation service maintained by Greenpeace and Gene Watch UK, has found contamination in three internationally cultivated GM food and feed crops – oilseed rape, soya and maize – since 1997.<sup>8</sup> Therefore, the contamination becomes a significant threat at all stages, from GM food production to consumption.

The components of national food safety systems such as safety assessment, labelling procedures, monitoring and surveillance, information sharing, liability and redress, and the requisite institutional mechanisms to carry out the relevant stages of GM food import and domestic production has been identified through the thorough analysis of various international instruments and domestic legislation. Out of these, the author of this article found that safety assessment and the liability and redress mechanism are of utmost importance in relation to the domestic introduction and import of GM food and derivatives which should be given prime importance. Therefore, the present study was undertaken to examine the extent of development of safety regulations and the liability framework for GM food and derivatives from an international perspective with a specific focus on BRICS countries.

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<sup>4</sup> John E. Losey, *Transgenic Pollen Harms Monarch Larvae*, 399(6733) *Nature* 214 (1990).

<sup>5</sup> Stanley W.B. Ewen & Arpad Pusztai, *Effect of Diets Containing Genetically Modified Potatoes Expressing Galanthus nivalis lectin on Rat Small Intestine*, 354(9187) *The Lancet* 1353 (1999).

<sup>6</sup> Elizabeth Duall, *A Liability and Redress Regime for Genetically Modified Organisms under the Cartagena Protocol*, 36(1) *George Washington International Law Review* 173 (2004).

<sup>7</sup> Julie A. Nordlee et al., *Identification of a Brazil-Nut Allergen in Transgenic Soybeans*, 334(11) *New England Journal of Medicine* 688 (1996).

<sup>8</sup> Becky Price & Janet Cotter, *The GM Contamination Register: A Review of Recorded Contamination Incidents Associated with Genetically Modified Organisms (GMOs), 1997–2013*, 1(5) *International Journal of Food Contamination* 1 (2014).

## 1. Commercial Status of GM Food in BRICS Countries

The research and development of GMOs in Brazil commenced in the 1990s, when farmers began to cultivate GM soybeans imported from Argentina. The first GM product was commercialised in 1995. Since then, the adoption and cultivation of GMOs in Brazil has increased to an average of 78% of total coverage of cotton, corn and soybean in 2015. So far, the CTNBio (Comissão Técnica Nacional de Biossegurança/ National Technical Committee on Biosafety) has approved 50 types of GMOs of which the majority (35 of them) are plants, including cotton, soybean and corn. Brazil is a major exporter of agricultural commodities and food products (worth US\$4.8 billion) to the United States and imports agricultural products, commodities for example such as wheat, and other products (worth US\$1.7 billion). Moreover, Brazil is the major exporter of GM cotton, corn and soybeans.<sup>9</sup> China and the European Union are the major importers of GM cotton and soybean.

In the case of China, GM technology has been used in the area of pharmaceuticals, agriculture and the food processing industry. It is the first developing country to grant commercial approval for viral-resistant tobacco plants, in 1988. In the period between 1991 and 2002, the Chinese Ministry of Agriculture granted six licenses for the commercial production of GM food crops including two varieties of cotton, and two varieties of tomato, sweet pepper and petunias. The cultivation of GM crops has been successful, with 3.9 million hectares involved. In 2014, China was ranked sixth among the 28 countries cultivating GM crops. According to a National Scientific Research Plan 2008, research and development through GM technologies were designated by the Chinese government as one of the 16 major areas targeted for major breakthroughs by 2020. China is a major importer of cotton, papaya, soybean and corn from the United States; and the annual import of soybean was approximately 70 million tonnes in 2014. Moreover, the country also imports millions of tonnes of soybean oil as a feed for farmed pigs and use as vegetable oil.<sup>10</sup>

Consumer concerns in relation to GM have recently been increasing, which led the country to reject shipments of GM corn from the United States. China returned 8,870,000 tonnes of US corn shipments tainted with a GM strain which was not approved because of its unapproved MIR 162, a strain of insect-resistance GM corn. The country intends to commence GM research and development rather than concentrate on imports. It thus has started to master the technology and develop its own industry. In the case of South Africa, research and development of GM has been successful in the last three decades. It is considered to be the only country on the African continent to embrace GM technologies, in order to deal with famine and

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<sup>9</sup> Clive, *20<sup>th</sup> Anniversary (1996 to 2015)*, *supra* note 1.

<sup>10</sup> Top China Imports from the World (Feb. 20, 2018), available at [http://www.worldsrichestcountries.com/top\\_china\\_imports.html](http://www.worldsrichestcountries.com/top_china_imports.html).

drought. South Africa acknowledges the utilisation of such technologies to increase crop production and to reduce the import of grains from other nations.<sup>11</sup>

Along with various other agricultural technologies, the South African government showed its positive intention in adopting GM technology. It is the ninth largest producer of first-generation GM crops. The first field trial approval of GM crops occurred in 1989, followed by the commercial approval of insect-resistance GM cotton and maize in 1997. Since then, there has been an increase in the cultivation and commercialisation of GM. For instance, the cultivation of GM maize amounted to 72% in 2011–2012.<sup>12</sup> Currently, commercialised GM food crops include maize, cotton and soybean. Canola oil is the only product which has been imported into the continent in the form of a GM derivative.

In 2014, three new types of GM, including two varieties of GM corn, were allowed for general release into the environment. In the same year, 25 field trial approvals were allowed for experimental purposes. Four hundred two permits were issued for import and export of GM crops that included 244 for exports, 120 for imports, 25 for trials, 3 for contained use, 6 for commodity clearance and 3 for general release.<sup>13</sup> Six commodity clearances for import were allowed after conducting appropriate safety assessment tests intended for food and feed use. This includes five GM varieties, namely corn, soybean, cotton, rice and rapeseed. Furthermore, the commercialisation of insect- and drought-resistant GM corn was expected for release in 2017.

In February 2016, Russia denied the import of soybean and corn from the United States because most of the crops developed there are found to be genetically modified.<sup>14</sup> Among the BRICS countries, in addition to South Africa, Brazil, China and India are promoting indigenous biotechnology industries and adopting greater use of biotechnology approaches in public and private research institutes. Russia took the political stand that it neither will import nor domestically produce GM foods or derivatives in any form. China and India are the most advanced leading crop producers in Asia. They represent 45% and 49%, respectively, of the total area of 76.4 million hectares of GM crops planted in the last 15 years of commercialisation. Among African countries, South Africa is the largest producer of GM crops and the commercialised varieties are Bt maize, Bt soybean and Bt cotton. India and China

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<sup>11</sup> The Food Security Forecast estimated that 2.9 million people needed immediate food aid before March of 2016 in the region of Malawi.

<sup>12</sup> Genetically Modified Organism Presentation, Department of Trade and Industry, 13 September 2013 (Feb. 20, 2018), available at <https://www.thedti.gov.za/parliament/2013/GMOS.pdf>.

<sup>13</sup> South Africa-Republic of Agricultural Biotechnology Annual, Global Agricultural Information Network Report, USDA Foreign Agricultural Service, 8 December 2013 (Feb. 20, 2018), available at [http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual\\_Pretoria\\_South%20Africa%20-%20Republic%20of\\_8-12-2013.pdf](http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Pretoria_South%20Africa%20-%20Republic%20of_8-12-2013.pdf).

<sup>14</sup> William Engdahl, *Russia Bans US GMO Imports*, Global Research, 29 February 2016 (Feb. 20, 2018), available at <https://www.globalresearch.ca/russia-bans-us-gmo-imports/5510933>.

contributed to improving agricultural productivity and enhancing food production with the advent of GM crops.<sup>15</sup> While non-food crops have been adopted in a number of Asian countries, there is a varied and limited introduction of GM-based food crops. Investment in public-sector research and development for GM foods is high in developing countries such as Brazil, China, India and South Africa.<sup>16</sup> Among the BRICS countries, China was the first to commence activities related to research and development of GM food crops, in 1988, followed by South Africa and Brazil in 1997 and 1998, respectively.<sup>17</sup>

Papaya is the only GM food crop approved for commercialisation in China. As a result, safety certificates for GM plants such as cotton, rice, maize, tomatoes, sweet pepper, papaya, poplar seeds and petunias have been issued for production. The Chinese Ministry of Agriculture has approved GM tomatoes (1997), cotton (1997), petunias (1999), sweet pepper and chili pepper (1999), papaya (2006), rice (2009) and corn (2009).<sup>18</sup> Only soybean, corn, rapeseed, cotton and sugar beets have been allowed to be used as raw material for domestic processing. In contrast to China, India has not approved any GM food so far. However, limited field trial approvals have been allowed for GM rice, mustard, cotton, chickpea and brinjal by GEAC, the apex body for granting regulating approvals for GM food crops of India in 2014.<sup>19</sup> So far, 60 applications have been permitted approvals for field trials to various public, private sector and multi-national corporations in India. For five GM food crops, i.e. brinjal, maize, rice, chickpea and cotton, field trial approvals were given by the government of Maharashtra in January 2015. The report of the sub-committee of GEAC<sup>20</sup> recommends the commercialisation of GM mustard (Dhara Mustard Hybrid (DMH)-11) for domestic cultivation.

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<sup>15</sup> Muthukrishnakumar Kandasamy & Padmavati Manchikanti, *Transgenic Crop Research and Regulation in India: Whether Legislation Rightly Drives the Motion?*, 20(4) *Journal of Commercial Biotechnology* 17 (2014); see also, Peter Newell, *Lost in Translation? Domesticating Global Policy on Genetically Modified Organisms: Comparing India and China*, 22(1) *Global Society* 115 (2008).

<sup>16</sup> Tao Tan et al., *The Impact of GMO Safety Regulations on Chinese Soybean Exports*, 3(3) *Journal of Basic and Applied Scientific Research* 164 (2013).

<sup>17</sup> Jikun Huang et al., *Agricultural Biotechnology Development, Policy and Impact in China*, 37(27) *Economic and Political Weekly* 2756 (2002).

<sup>18</sup> Canfa Wang & Wenxuan Yu, *Agro-GMO Biosafety Legislation in China: Current Situation, Challenges, and Solutions*, 13(4) *Vermont Journal of Environmental Law* 865 (2011–2012).

<sup>19</sup> Xiao Zhi Lim, *Indian Biotech Regulator Approves Field Trials for 15 GM Crops, Draws Harsh Criticism*, Genetic Literacy Project, 23 July 2014 (Feb. 20, 2018), available at <https://geneticliteracyproject.org/2014/07/23/indian-biotech-regulator-approves-field-trials-for-15-gm-crops-draws-harsh-criticism/>.

<sup>20</sup> 126<sup>th</sup> meeting of the Genetic Engineering Appraisal Committee (GEAC) convened on 4 January 2016 constituted a sub-committee comprised of health expert Dr. B. Sesikeran, MD in Pathology, Former Director, National Institute of Nutrition (NIN) and Indian Council of Medical Research (ICMR) and the current Chairman of the Review Committee on Genetic Manipulation (RCGM).

In the foregoing analysis it is observed that South Africa was the earliest to introduce both GM food and derivatives. The other countries, except India, introduced GM food either through domestic cultivation or import. In this context, the development of legislation as well as regulation of the activities of GM food from the sphere of manufacturing to human consumption is essential.

## **2. Governmental Policies Towards GM Food: Promotion of Restriction**

Understanding policy perspectives provides a view into the favourable or restrictive approaches, measures, socio-economic factors, reforms, standards and initiatives of governments. There are potential policy reactions across different nations about GM food. In China, the policy is specially focussed on the promotion of self-development rather than import. In this regard, the Ministry of Agriculture strengthened research into agricultural GMOs with the focus on safety assessment, regulation and management of agricultural GMOs.<sup>21</sup> In early 2015, the Central Committee of the Communist Party of China and State Council made 32 concrete suggestions on how to foster the development of modern agriculture and rural community and to increase farmers' income. Emphasis was placed on the significance of food security and the importance of agriculture for socio-economic development while ensuring food safety and quality of agricultural products.

In Brazil, GM technology has been prioritised to promote sustainable development. The President of CTNBio believes that the adoption of GM technology in agriculture is necessary to overcome issues of tropical and humid climate that promote susceptibility to pests.<sup>22</sup> The Science and Technology Programme aims principally at the development of technologies applied to health, agriculture and the environment, and the development of genetically modified organisms has been one of the focus areas.<sup>23</sup> The primary objective of the Biosafety Policy of Brazil is to ensure an appropriate level of protection to human, animal and plant health and to the environment, and the safe utilisation of GM technology. The policy established the framework to extract the maximum benefit from GM technologies and to promote the industries involved in activities of GMOs. It further believes that there is an urgency in bringing biosafety measures not only to regulate GMOs, but also to

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<sup>21</sup> Proposal in Response to 12<sup>th</sup> Five-Year Plan for Development of Agricultural Science and Technology, 30 December 2011 (Feb. 20, 2018), available at [http://www.moa.gov.cn/zwl/m/zcfg/nybgz/201112/t20111231\\_2449779.htm](http://www.moa.gov.cn/zwl/m/zcfg/nybgz/201112/t20111231_2449779.htm).

<sup>22</sup> Joana Ferreira, *GMOs, A Global Debate: Brazil, Second Largest GMO Producer in World*, EPOCH Times, 8 July 2013 (Feb. 20, 2018), available at <http://www.theepochtimes.com/n3/162906-gmos-a-global-debate-brazil-second-largest-gmo-producer-in-world/>.

<sup>23</sup> Leda Mendonça-Hagler et al., *Trends in Biotechnology and Biosafety in Brazil*, 7 Environmental Biosafety Research 115 (2008).

GMOs intended for food, feed or processing, irrespective of whether they are locally produced or imported from abroad.

In the case of South Africa, the policy has been to ensure safe utilisation of GM technology for strengthening the country's economy as well as to enhance the livelihood of its citizens, keeping in view the protection of human health and the environment. GM regulations have been developed with zero risk to 1% risk based on the prevailing crop and climatic conditions. Recently, permits for the import of GM maize to avert a food crisis and severe drought have been considered. In fact, 90% of maize cultivation in the country has already been produced through GM technologies. But in the case of India, the government banned the commercial cultivation of GM food crops and allowed only the GM crop Bt cotton, not intended for human consumption, since 2002. In 2009, the Genetic Engineering Appraisal Committee (GEAC) of India granted approval for field trial experiments on the commercial cultivation of Bt brinjal.<sup>24</sup>

Due to widespread public uproar and opposition from anti-GM activists, a moratorium was placed in 2010. While Bt brinjal is not allowed by the regulators on the basis of safety considerations, the commercial approval of home-grown GM mustard is in the pipeline. In Brazil and South Africa, GMOs were introduced when there was no policy or legislative framework in place. China concentrates more on home-grown GM food crops and its domestic production, while India is in the process of making decisions on both home-grown GM food crops and to some extent the import of GM derivatives.<sup>25</sup> The analysis of the food safety components and the regulatory mechanism for the domestic production or import of GM food and derivatives is an important consideration in relation to the countries. In order to identify the components of the national food safety system and its regulatory measures, the thorough analysis of international trade regulations is essential as GM food and derivatives becomes a good in the international trade arena due to the process of globalisation.

### **3. International Trade Regulations on GM Food and Derivatives**

International trade of agricultural products is based on the commodity system.<sup>26</sup> Food as a commodity of international trade is a growing market. The global trade in food products will continue to expand rapidly with the introduction of

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<sup>24</sup> Lim, *Indian Biotech*, *supra* note 19.

<sup>25</sup> Vandana Shiva, *GMO-Mustard Bio-Safety Assessment: A Scientific Fraud on the Nation*, 13 May 2017 (Feb. 20, 2018), available at <http://vandanashiva.com/?p=491>.

<sup>26</sup> Directorate-General for Agriculture, The European Commission, *Economic Impacts of Genetically Modified Crops on the Agri-Food Sector*, Working Document (Feb. 20, 2018), available at [https://ec.europa.eu/agriculture/publi/gmo/full\\_en.pdf](https://ec.europa.eu/agriculture/publi/gmo/full_en.pdf).

GM food in the commercial food chain and greater participation of most of the developing countries.<sup>27</sup> Despite the concerns, the level of acceptance of GM food and derivatives is growing higher since its inception in 1996.<sup>28</sup> The international regulations which apply to conventional foods will be generally suitable for GM foods also. International conventions, multilateral agreements and policy decisions implemented by international organisations and international standards-setting bodies have been analysed in respect of international trade in GM foods. The Sanitary and Phytosanitary (SPS) agreement negotiated under the World Trade Organisation (WTO), and the Cartagena Protocol on Biosafety are the two major international instruments that govern the transboundary trade in agricultural and food products containing genetically modified organisms. The analysis of safety regulations and the liability framework will be done based on the consideration of those international instruments.

### **3.1. Safety Regulations**

This section examines the international liability framework whose general structure provides an appropriate starting point for safety assessment and the development of methods to ensure the safety of products. The section is an attempt to review the extent of the development of the international regulatory framework on safety assessment which governs the domestic regulation and the transboundary trade of GM food and derivatives.

#### *3.1.1. WTO Agreement*

International trade received a major boost with the initiation of the WTO.<sup>29</sup> The primary objective of establishing the WTO was to regulate international trade and to effectively utilise the world's resources without any trade restrictions.<sup>30</sup> The WTO provides a legal foundation and institutional mechanism for dealing with the multilateral trading environment. It ensures precise measures through its agreements for assisting the manufacturers of goods and services, exporters and importers to conduct business for free and fair trade. It strongly believes that the lowering of trade barriers will always assist in encouraging international trade and commerce.

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<sup>27</sup> Food and Agriculture Organization of the United Nations, *The State of Agricultural Commodity Markets: Trade and Food Security: Achieving a Better Balance Between National Priorities and the Collective Good (2015–2016)* (Feb. 20, 2018), available at <http://www.fao.org/3/a-i5090e.pdf>.

<sup>28</sup> Ed Wallis, *Fish Genes Into Tomatoes: How The World Regulates Genetically Modified Foods*, 80 *North Dakota Law Review* 421 (2004).

<sup>29</sup> Marcos A. Orellana, *Evolving WTO Law Concerning Health, Safety and Environmental Measures*, 1(1) *Trade, Law and Development* 103 (2009); Gregory Messenger, *The Development of World Trade Organisation Law: Examining Change in International Law* (Oxford: Oxford University Press, 2016).

<sup>30</sup> Objective of the World Trade Organisation (WTO). The WTO is an inter-governmental organisation created to regulate international trade; it was established in 1995.

First of all, in the context of safety regulation, the SPS Measure laid down by the countries through Art. 5.1 of the SPS Agreement shall be justified with sufficient scientific risk assessment techniques for preventing unsafe food entering into its markets.<sup>31</sup> In practice, the principles laid down in this Principal Document, i.e. the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology, CAC/GL 44-2003, adopted in 2003 and amended in 2008 and 2011, are to be followed along with the Codex Working Principles while conducting the risk analysis, i.e. the Working Principles for Risk Analysis for Food Safety for Application by Governments, CAC/GL 62-2007. The main scope of these Working Principles is to provide adequate guidance to the national governments in matters of three components of risk analysis, such as risk assessment, risk management and risk communication. The scientific data for the safety assessment of foods shall be derived from the development of the product, existing scientific literature, available technical information, and from independent scientists, regulatory authorities and other international bodies. In the *EC-Biotech* case,<sup>32</sup> the panel referred to the Codex Guidelines for determining the safety assessment of GM foods and derivatives. Legal recognition to the Codex guidelines has been given through the case.

The members of the WTO shall base their food safety measures according to Codex Standards through the application of the SPS Agreement. The standards established by the Codex Alimentarius Commission have evolved as an international guideline for the safety assessment of GM foods by principle of risk analysis. The guidelines are formulated through case-by-case analysis that applies to the conventional counterpart. The reason for the comparison of the conventional counterpart is because of its history of safe consumption. Hence, it is used as a baseline for the safety assessment of GM food and derivatives. The principle of substantial equivalence has evolved among the international community for facilitating the comparison between GM food and its conventional counterpart. Substantial equivalence is the starting step in the process of safety assessment. Through the substantial equivalence principle, the differences in composition, agronomical and morphological characters have been identified to assess any endangering activities to human health.

If any member country deviates from this standard, it should be on the strength of relevant scientific evidence and through adequate risk-assessment techniques.<sup>33</sup> The higher grade of protection shall be set by international standards, recommendations

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<sup>31</sup> See Preamble of the SPS Agreement, which states that, "Reaffirming that no Member should be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health, subject to the requirement that these measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members where the same conditions prevail or a disguised restriction on international trade."

<sup>32</sup> European Communities – Measures Affecting the Approval and Marketing of Biotech Products, WT/DS 291/R, WT/DS 292/R and WT/DS 293/R, 2006.

<sup>33</sup> Articles 2, 3 and 5 of the SPS Agreement.

and guidelines. However, the Principal Document does not take into account the relevant environmental, ethical, moral and socioeconomic aspects of research, development, production and marketing of foods. It is evident that the Codex presently harmonises the regulatory issues of risk analysis surrounding GM foods. Although, the principles and guidelines of the Codex<sup>34</sup> are legally non-binding in nature, through the mechanism of the WTO's SPS Agreement, every member of the WTO is obliged to comply with the recommendations.

There is an ongoing debate internationally on the capacity to predict and avoid the adverse effects on human health for the necessary introduction of GM food and derivatives. While the WTO limits freedom for every individual nation in imposing trade restrictions, the Cartagena Protocol on Biosafety is the only international agreement that focuses on national objectives rather than concentrating on trade restrictions. It stresses the importance of protecting biodiversity, the environment and human health.

### 3.1.2. *Cartagena Protocol on Biosafety*

The need and modalities for setting out a protocol to cover the transboundary trade aspects of GM foods, especially, with the specific purpose of protection of human health and the environment, arose as per Art. 19.3 of the Convention on Biological Diversity (CBD).<sup>35</sup> During the Second Conference of the Parties (COP-2) to the CBD in 1995, a Biosafety Working Group (BSWG) was established to implement the provisions of Art. 19.3.<sup>36</sup> The Working Group came up with the idea of a Biosafety Protocol, after several rounds of negotiations between 1996 and 2000. The Cartagena Protocol on Biosafety (Biosafety Protocol) entered into force in 2003. Currently, there are about 170 member countries that are parties to the Biosafety Protocol.

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<sup>34</sup> For maintaining uniformity in the safety assessment of GM foods in the context of international trade, United Nations (UN) agencies such as the World Health Organisation (WHO) and the Food and Agricultural Organisation (FAO) together established and administered the international standard-setting body, i.e. Codex Alimentarius Commission (CAC) in 1963. CAC is an inter-governmental standard-setting organisation of the FAO and WHO which promotes international guidelines for the safety assessment of foods including foods derived from genetically modified organisms and genetically engineered plants. It consists of three committees: Codex Committee on General Principles (CCGP), Codex Committee on Food Labelling (CCFL) and Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology (Task Force). Of these, CCGP is entitled to develop a set of standards concerning safety regulation, and CCFL develops guidelines to deal with the labelling aspects of GM food and derivatives.

<sup>35</sup> The Convention on Biological Diversity (CBD) was negotiated and signed in 1992 at the United Nations Conference on Environment and Development (the Rio "Earth Summit") and came into enforcement in 1993. As of now, 196 countries are parties to the Convention. Article 19.3 states: "Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity."

<sup>36</sup> Second Ordinary Meeting of the Conference of the Parties to the Convention on Biological Diversity held in Jakarta, Indonesia on 6 to 17 November 1995.

The Biosafety Protocol is an international environmental agreement that established the global framework for the regulation of LMOs,<sup>37</sup> including GM food. It laid an important obligation on its member countries concerning the transboundary movement of GM food and derivatives. The primary objective of the Biosafety Protocol was *to ensure an adequate level of protection for the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may possess adverse effects on the conservation and sustainable use of biological diversity with a particular focus on the transboundary movements*. It is the only international instrument that specifically addresses the negative aspects of GM food and derivatives in regard to human health and the environment.<sup>38</sup> Also, it creates an obligation on the member states to develop regulations to address safety concerns relating to the trade of GM foods. The inclusion of the precautionary principle is hailed as one of the principal achievements of the Biosafety Protocol. It mandates that countries observe a cautious approach and restrict imports of GM food in the case of scientific uncertainty.

The important feature of the Biosafety Protocol is the incorporation of the Advance Informed Agreement (AIA). The purpose of this procedure is to provide an opportunity for the importing countries to address the safety concerns over GM in the context of international trade. Article 7.2 of the Biosafety Protocol also prescribes that the AIA procedure applies to the first intentional transboundary movement of LMOs for the deliberate release into the environment. While the transboundary movement of LMOs intended for direct use as food, feed or processing is not subject to this particular procedure, this will be governed by Art. 11 of the Biosafety Protocol.

During the pre-shipment period, the party of the export/exporter who intends to export their GM products has to obtain written consent from the party of the import/importer.<sup>39</sup> Based on Art. 10 of the Biosafety Protocol, the decision on notification shall be made within 15 days from the date of receipt of the notice and it shall be communicated to the party of export relating to approval or rejection of import. In general, the party intending to export must notify the same to the Biosafety Clearing House regarding the use of GM food and derivatives relating to the domestic use or placing on market shelves.

The parties shall also make reference to applicable national legislation, regulations and guidelines to the Biosafety Clearing House. Thus, it is provided that the parties to the Protocol will have the freedom to decide on the domestic regulatory framework

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<sup>37</sup> The terms Living Modified Organism (LMO) and Genetically Modified Organism (GMO) are interchangeably used in the various international references.

<sup>38</sup> Article 15 and Annexure III of the Biosafety Protocol.

<sup>39</sup> Principle 15 of the Rio Declaration states: "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." The precautionary approach is reflected in various provisions of the Biosafety Protocol: Preamble, Arts. 1, 10.6, 11.8 and Annexure III.

applicable to the import of living modified organisms intended for direct use as food or feed, or for processing, subject only to the objectives of the Protocol. It is observed that the scope of Biosafety Protocol is not well defined with regard to GM foods.<sup>40</sup> Generally, GM foods are included in the broad scope of the Biosafety Protocol only when LMOs are capable of or replicate genetic material.

### **3.2. Liability Framework**

This section examines the international liability framework whose general structure provides an appropriate starting point for liability and redress in dealing with damages arising out of the introduction and import of GM food and derivatives.

#### *3.2.1. Basel Convention and Basel Liability Protocol*

The most comprehensive environmental agreement that deals with hazardous substances is the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (Basel Convention).<sup>41</sup> Article 12 of the Basel Convention enumerates the cooperation from member countries to develop rules and procedures in the field of liability and compensation for environmental damage arising out of the transboundary movement of hazardous waste and its disposal. Accordingly, Art. 12 of the Basel Convention acts as an enabling clause to develop the Protocol on Liability and Compensation for Damage Resulting from Transboundary Movements of Hazardous Wastes and Their Disposal (Basel Liability Protocol). The Basel Liability Protocol was negotiated and adopted in 1999.<sup>42</sup>

The important objective of the Basel Liability Protocol was to establish a comprehensive liability regime inclusive of the rules and procedures for providing third-party liability, environmental liability and compensation for damage arising out of the transboundary movement of hazardous waste. Most of the considerations being given to the third-party liability and environmental liability, which are closely associated with the damages, occur during the transboundary movement of GM food and derivatives. As contemplated in Art. 4 of the Basel Liability Protocol, the

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<sup>40</sup> Debra M. Strauss, *Genetically Modified Organisms in Food: A Model of Labeling and Monitoring with Positive Implications for International Trade*, 40 *International Lawyer* 95 (2006).

<sup>41</sup> The Basel Convention was negotiated and adopted in 1989 and came into force in 1992. The significant objective of the Basel Convention was to place a restriction to deal with the transboundary movement of hazardous waste and its proper disposal without causing any threat to human health and the environment; see also, Guido Fernando Silva Soares & Everton Vieira Vargas, *The Basel Liability Protocol on Liability and Compensation for Damage Resulting from Transboundary Movements of Hazardous Wastes and Their Disposal*, 12(1) *Yearbook of International Environmental Law* 69 (2002).

<sup>42</sup> Peter Lawrence, *Negotiation of a Protocol on Liability and Compensation for Damage Resulting from Transboundary Movements of Hazardous Wastes and Their Disposal*, 7(3) *Review of European Community and International Environmental* 249 (2002); see also, Jerrold A. Long, *Protocol on Liability and Compensation for Damage Resulting from the Transboundary Movements of Hazardous Wastes and Their Disposal*, 11 *Colorado Journal of International Environmental Law and Policy* 253 (1999).

legal framework developed in other multilateral agreements that deal with strict liability are considered.

Article 4 of the Basel Liability Protocol provides a basis for the *strict liability* doctrine and also the channelling of liability to a certain extent. According to the strict liability doctrine mentioned in the Basel Liability Protocol, the claimant is entitled to file a case for damage suffered during the process of transboundary trade with full compensation. In general, the notifier will be held liable and in some cases the exporter is liable.<sup>43</sup> If the importing state and the exporting state are contracting parties, then the “notifier” is held liable. But, the exporter is liable for any case where notification did not enter into the picture.<sup>44</sup> After determining the parties to the claim, then comes the definition of damage, because it was the basis for the subject matter of the claim. The definition of “damage” is enumerated in Art. 2(c) of the Basel Liability Protocol:

any loss of life or personal injury; loss or damage to property other than property held by the person liable.

In addition to strict liability, the Basel Liability Protocol also elaborates the fault-based liability system. As envisaged in Art. 5 of the Basel Liability Protocol, whosoever is involved in the causation of damage is said to be liable. Though the Basel Liability Protocol sets out a procedure of strict liability and fault-based liability for hazardous substances, it does not directly deal with GM food and derivatives.

### 3.2.2. Cartagena Protocol on Biosafety and Its Supplementary Protocol

The Cartagena Protocol on Biosafety was the first international environmental agreement modelled after the Basel Convention<sup>45</sup> to ensure the safe handling, package and distribution of LMOs with the primary focus on the transboundary trade of LMOs including GMOs and GM food and derivatives. Though the agreement has been successful in certain regulatory innovations in the case of GM food and derivatives, the language of the agreement is silent on the matter of substantial provisions of standards of liability and redress mechanisms to deal with damages arising out of import or export of GM foods and derivatives. But the legal obligation to develop the rules on liability and redress concerning GM food is found in Art. 27 of the Cartagena Protocol on Biosafety, which reads as follows:<sup>46</sup>

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<sup>43</sup> Article 14, Insurance and other financial guarantees, Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, 27 May 2014.

<sup>44</sup> There is no precise definition of “notifier” in the Basel Liability Protocol. The definition shall be deduced from the Basel Convention and Art. 4 of the Basel Liability Protocol.

<sup>45</sup> Robert Paarlberg, *A Dubious Success: The NGO Campaign against GMOs*, 5(3) *GM Crops & Food* 223 (2014); see also, Paul E. Hagen & John B. Weiner, *The Cartagena Protocol on Biosafety: New Rules for International Trade in Living Modified Organisms*, 12 *Georgetown International Environmental Law Review* 697 (2000).

<sup>46</sup> Emphasis added.

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analysing and taking due account of the ongoing processes in international law on these matters, and shall endeavour to complete this process within four years.

The just-quoted clause of the Biosafety Protocol enables the parties to formulate procedures relating to liability and redress so as to deal with damage arising out of the import and export of GM food and derivatives. This particular clause necessitates the importance of the development of the liability provisions under a single legislation to deal with the damage arising in the transboundary trade of GM food and derivatives. After discussion under the purview of Cartagena Protocol on Biosafety, the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress (N-KL Protocol) was negotiated for dealing with the issues of liability concerning LMOs, including GMOs and GM foods.<sup>47</sup> The principal objective of the N-KL Protocol is to set internationally agreed rules and procedures to prevent and remedy damage to the biodiversity for the injury caused by the transboundary movement of LMOs. The salient feature of the N-KL Supplementary Protocol includes response measures, administrative approaches, civil liability and state responsibility.

According to Art. 5 of the N-KL Protocol, member countries are authorised to formulate response measures for operators so as to keep the designated competent authority informed about incidents of damage caused by the transboundary movement of GM foods. It is the responsibility of the competent authority to consider appropriate measures to evaluate the cost of damage. Though it may be regarded as a fundamental phenomenon under the aegis of the N-KL Protocol to protect biodiversity, it offers a different fashion in dealing with damage such as personal injury or property damage. Therefore, the Food Business Operator (FBO) as well as the competent authority holds an additional responsibility to consider the procedures for dealing with the damage. In this connection, the response measures offered under the particular clause will be a full choice of action for the countries to develop a defensive or restorative mechanism in their domestic legislation. When there is a sufficient likelihood of damage or at the occurrence of harm, the member countries shall fix the procedures for the operator to take significant action to deal

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<sup>47</sup> Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety, United Nations Environment Program, Secretariat of the Convention on Biological Diversity, Montreal, Canada (2011). As of November 2016, 36 member countries have deposited the instrument for acceptance, accession and ratification, which requires four more countries in order to enter into force. Parties to the Cartagena Protocol and its Supplementary Protocol on Liability and Redress (Feb. 20, 2018), available at <https://bch.cbd.int/protocol/parties/#tab=1>.

with the loss.<sup>48</sup> In this way, the operator has to undertake three-pronged action, such as reporting the incident to the competent authority, evaluating the damage and considering appropriate measures mentioned in Art. 5.1. In the case of failure to discharge its duties, the competent authority must enter into operation and formulate a suitable procedure to deal with the damage and to offer a remedy for the victims. In such actions, the competent authority is entitled to recover the expenses it incurs.

It is a well-established principle that every country will safeguard its boundaries from harm caused by neighbouring countries.<sup>49</sup> Therefore, the state is accountable for every kind of damage caused during the transportation of GM food across its territories. An attempt has been made at the international level to introduce a uniform liability regime in the form of civil liability to deal with the damage arising out of the transboundary trade in GM food and derivatives. Nevertheless, member countries must formulate the standards of liability in their domestic laws on the basis of the economic, social and other political perspectives of the country. In this connection, Art. 12 of the N-KL Protocol enumerates the principle of civil liability through the judicial system of a country which considers the attachment of responsibility for any damage through the civil remedies. The civil remedies may be obtained by the victims by way of written petition to the designated administrative authorities. It is a kind of private litigation, where the injured party files a suit against the offenders, claiming damages without including the "State" as a party. The relief sought by the claimant must be in one of two forms: either it can be monetary compensation or an injunction to restrain the activities of the defendant. This reflects the principle that the injured person has the right of recourse in their national legal system against the person accountable for the damage.

According to the civil liability doctrine, every member country shall formulate rules and procedures of liability to deal with injury arising out of the transboundary trade of GM food and derivatives. The incorporation of standards of liability may be by way of amendment to existing legislation or through the introduction of specific laws to deal with the damage. In certain circumstances, the combination of both in general and specific laws will serve the purpose.<sup>50</sup> Though the N-KL Protocol deals with the loss concerning the transboundary trade of GM food and derivatives, the standards of liability for damage occurring at the domestic production location needs to be developed. Moreover, the attempt by the N-KL Protocol failed in its uniform liability regime because the standards of liability are bound to differ. Even though

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<sup>48</sup> Article 5.3 of the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress.

<sup>49</sup> Aaron Schwabach, *Transboundary Environmental Harm and State Responsibility: Customary International Law*, Encyclopedia of Life Support Systems (Feb. 20, 2018), available at <https://www.eolss.net/Sample-Chapters/C14/E1-36-02-02.pdf>.

<sup>50</sup> Article 12(2) of the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress.

the N-KL Protocol was unable to create rules, the obligation for transboundary trade remains an issue in the international arena. Moreover, there is a lacuna in the N-KL Protocol in the determination of liability of the parties to the suit.

Many international agreements contain provisions calling for the development of liability regimes, but so far few systems have been developed. Most international agreements in the area of transboundary environmental damage utilise a civil liability regime where private parties predominantly control the activities at issue. The definition of GMOs included in the Cartagena Protocol on Biosafety includes the activity concerning LMOs intended for the direct use of food, feed or processing.<sup>51</sup> The damages caused by processed GM products are also relevant in the definitional clause, which is excluded from the scope of damage. The adoption of individual liability regimes in every GM importing country will be the necessary complement to the international law system. This is because the international agreements provide freedom for the countries to develop their standards in dealing with damages arising out of the introduction or import of GM food and derivatives. In addition to the development of international law on liability, there is a possibility for the development of principles of liability in the legislation of developed as well as developing countries. In this aspect, the domestic legislation of certain developing countries needs to be analysed to bring out the extent of development of liability mechanisms in dealing with damages concerning GM food and derivatives.

#### **4. Leading Judicial Pronouncements on the Adaptability of Precautionary Approach in Domestic Legislation**

The precautionary principle has become the fundamental component of international environmental policy.<sup>52</sup> It was proclaimed at the United Nations Conference on Environment and Development, popularly known as the Rio Declaration in 1992. More particularly, Principle 15 of the Rio Declaration reads as follows:<sup>53</sup>

In order to protect the environment, the precautionary principle 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.

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<sup>51</sup> See, *Procedure for Living Modified Organisms intended for Direct Use as Food or Feed, or for Processing*, Art. 11 of the Cartagena Protocol on Biosafety.

<sup>52</sup> David Freestone & Ellen Hey, *Origins and Development of the Precautionary Principle in The Precautionary Principle and International Law: The Challenge of Implementation* (D. Freestone & E. Hey (eds.), Cambridge: Kluwer Law International, 1996).

<sup>53</sup> Rio Declaration on Environment and Development, United Nations Environment Programme, Rio de Janeiro, 3–14 June 1992.

This principle has been widely accepted in order to protect the environment and to prevent damage concerning GMOs where there is the existence of scientific uncertainty. Though the precautionary principle is hailed as one of the essential components of the Rio Declaration and the Cartagena Protocol on Biosafety, the adoption and justification is still unsettled in the international parlance.<sup>54</sup> On the other hand, the precautionary approach is considered to be a significant feature of the Biosafety Protocol in dealing with GM foods. Furthermore, in view of the absence of conclusive evidence relating to the long-term effects of GM foods on human health, it is most appropriate for the a developing country to adopt a precautionary approach.

The application of the precautionary principle was challenged in the case of *Association Greenpeace France and Others v Ministère de l'Agriculture et de la Pêche and Others*,<sup>55</sup> before the European Court of Justice in 2000. In this case, the petitioner argued that the decision had to be taken by the European Commission only on the basis of the evaluation of the application in the context of safety assessment studies. Therefore, complete freedom was given to the national authorities to decide the application on the basis of the precautionary rule. But the European Commission employed its powers to annul the authorisation, whereas the national authorities are the ones who are competent to issue such orders. This approach seems to be in conflict with the precautionary principle because this policy provides every Member State an opportunity to raise objections concerning any adverse effect on human health or the environment. To add to the context, the interpretation of Art. 13(4) of the Council Directive 90/220 states that the national authority had to be given adequate opportunity to raise an objection concerning a decision of the Commission.

There are other instances to show that the precautionary approach is not widely accepted due to the defence available against the concept in different international instruments. For instance, the *EC Biotech* case<sup>56</sup> is pertinent for understanding the implications of the international trade of GM products and the adoption of the precautionary approach in domestic legislation. The United States alleged that the de facto moratorium imposed by the European Union for 27 GM products from 1999 to 2003 was found to be a trade-restrictive measure, which is contrary to the provisions formulated under the SPS Agreement. The United States generally does not support the precautionary principle as a rationale for food safety regulation, particularly within the international context.<sup>57</sup> Furthermore, in this case, the complainants contended that the precautionary approach should be available only for a temporary period as per Art. 5.7 of the SPS Agreement. However, the respondent, i.e. the EU, defended

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<sup>54</sup> Orellana 2009.

<sup>55</sup> Case C-6/99(2000).

<sup>56</sup> European Communities – Measures, *supra* note 32.

<sup>57</sup> Spencer Henson & Julie Caswell, *Food Safety Regulation: An Overview of Contemporary Issues*, 24(6) Food Policy 589 (1999).

itself by raising the argument that the precautionary principle was considered to be a general principle of international law.

Under the circumstances, the EU argued that the precautionary principle has been incorporated in various international agreements such as the Cartagena Protocol on Biosafety besides the domestic legislation of many countries.<sup>58</sup> But the Panel did not accept these arguments; rather, it delivered the opinion stating that the precautionary principle must not act as a defence for implementing trade-distortive measures concerning GM legislation.<sup>59</sup> In citing references from *Hormone Treated Beef*,<sup>60</sup> the Panel found that the relevance of the precautionary principle is still unsettled in international law. If the precautionary approach was not given adequate recognition across international jurisprudence, it is hard to develop the liability norms to deal with damage concerning the development of GM food and derivatives.

The components of the national food safety systems such as safety assessment, labelling procedures, monitoring and surveillance, information-sharing, liability and redress and the requisite of the institutional mechanism to carry out the relevant stages of GM food import and domestic production have been identified through the thorough analysis of various international instruments and domestic legislation. Out of these, safety assessment and the liability and redress mechanisms are of utmost importance for the domestic introduction and import of GM food and derivatives. Therefore, the present analysis has been carried out to review the existing regulatory measures and institutional set-up in relation to safety assessment and liability mechanisms in relation to the domestic introduction and import of GM food and derivatives in BRICS countries.

## 5. Critical Analysis

### 5.1. Safety Regulation in BRICS Countries

Safety has to be ensured not only from the point of manufacturing to market, but also from market to consumers, which includes many procedures to be followed to avoid risks to human health and the environment. It involves procedures to be adopted by the food manufacturers/exporters to comply with pre-market safety approvals and post-market monitoring mechanisms. In this relation, the present study has been attempted in order to compare and contrast the development of

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<sup>58</sup> Barbara Eggers & Ruth Mackenzie, *The Cartagena Protocol on Biosafety*, 3(3) *Journal of International Environmental Law* 525 (2000). The precautionary principle has its earlier reference from Preamble, followed in Arts. 1, 10.6, 11.8 and Annexure III of the Biosafety Protocol.

<sup>59</sup> Para. 7.89, Page 340 of Panel's Report in *European Communities – Measures Affecting the Approval and Marketing of Biotech Products WT/DS291/R, WT/DS292/R and WT/DS293/R* adopted on 21 November 2006.

<sup>60</sup> *European Communities – Measures Concerning Meat and Meat Products (Hormones)*, US – WT/DS26/19 (18 May 1999) and *Canada – WT/DS48/17* (20 May 1999).

policies, laws, regulations, guidelines and standards of food legislation and the development of institutional mechanisms in the said countries to deal with the food safety concerns related to GM food and derivatives. Furthermore, the procedures and guidelines for approval and the components of national food safety systems of BRICS such as safety regulations and liability have been analysed.

The safety assessment is an important criterion for identifying and evaluating the adverse effects of GM food and derivatives and their impact on human health. CTNBio of Brazil, National Agricultural GMO Biosafety Committee (BC) of China, Genetically Modified Food Safety Assessment Unit (GMFSAU) of India and Ministry of Agriculture are the appropriate authorities to conduct the safety assessment of the applications related to the introduction or import of GM foods and derivatives. In Brazil, the observance of the precautionary principle, the adoption of the scientific method and transparency of procedures are the guidelines for conducting methods of safety assessment. In China, the safety assessment has to be carried out at each and every stage of development. The procedures for safety assessment are of two kinds, viz. classification-based and evaluation-based. The classification shall be of GMOs in general, GM crops, GM foods in particular, whereas the evaluation shall be based on research, experiments, production, processing, business operations, import and export.

The principles of safety assessment are derived from the Codex guidelines for evaluating safety in both India and South Africa. The initial procedures for carrying out safety assessments of GM food and derivatives are to assess whether GM food is substantially equivalent to the conventional counterpart. The GM product shall be analysed for unexpected changes in a limited group of components such as toxins, nutrients or allergens that are present in the conventional food by the manufacturer. The safety and nutritional assessment are particularly important for developing nations like BICS because the consumption of such foods will cause significant changes in the dietary intake patterns and the food chain.

In addition to this, South Africa and India follow the procedures established in Annexure III of the Cartagena Protocol on Biosafety. The science-based safety assessment is acknowledged in Sec. 5(c)(i) of the GMO (Amendment) Act 2006. In India, subsec. 2 of Sec. 92 of FSSA 2006 provides the regulations concerning safety assessment under the purview of the Department of Biotechnology (DBT), the Ministry of Environment and Forest (MoEF) and the Indian Council of Medical Research (ICMR). Given the permissibility of the field trials and the increased international trade of GM foods approved for various countries, in 2008 the ICMR formulated guidelines for the safety assessment of GM foods, "Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants." In Brazil, the safety assessment is carried out as prescribed by Normative Resolution No. 5 of 2008. It defines safety assessment as a combination of procedures or methods to evaluate the potential effects of the planned release of GMOs and derivatives on human health.

The methods of safety assessment in South Africa, China, Brazil and India are more or less similar with certain differences in their approaches. Science-based assessment and case-by-case analysis to identify the source of genes, recipient organisms, and operation of GM have been considered. In addition to this, toxicological tests, allergenicity and nutritional analysis have been performed. Other than Brazil, all three countries follow the principle of substantial equivalence to bring out the difference between the GM products and conventional counterparts. In addition to the existing guidelines specified through the regulations, the authority of Brazil such as the CTNBio, the Ministry of South Africa and the FSSA of India shall make additional standards for the purpose of conducting a safety assessment (Sec. 13 of the Law No. 11,105 of 2005 of Brazil and Sec. 92(2) of the Food Safety and Standards Act 2006 of India).

If the derivative of GM food is already approved, it need not be subjected to safety assessment again in Brazil. So far, the Ministry of Agriculture in China has issued a Safety Certificate for five GM food crops: soybean, corn, tomatoes, rapeseed and cotton, in 2010. Furthermore, it approved 49 laboratories for carrying out safety assessment. The legislature of Brazil highlights the importance of transparency in approval procedures, whereas transparency in the approval process is more or less followed in South Africa and India. As per Sec. 18(2) of the GMO (Amendment) Act 2006, the report of science-based risk assessment shall not be kept confidential, and it shall be disclosed to the general public for the purpose of receiving their comments.

In addition to the safety assessment, safety management is an important aspect for considering an application for an activity concerning GM food and derivatives. The only country that put into effect the measures relating to safety management is South Africa. The Executive Council of South Africa proposed safety management measures along with the application. Regulation 7 is the appropriate standard to prescribe the procedures for safety assessment, but it did not prescribe any standards for safety management; rather, it includes measures on containment and confinement of GMOs, including GM food and derivatives, and rules covering activity such as storage, disposal, cleaning of equipment, monitoring for compliance, restriction of unlawful access, management and maintenance of records, etc. Along with the requisites mentioned in Regulation 7, the applicant has to follow Art. 16 of the Cartagena Protocol on Biosafety in prescribing safety management measures. States need to ensure appropriate measures to prevent unintentional transboundary movement and unauthorised environmental release without conducting a safety assessment to ensure safety and security to human health.

BRICS countries face challenges in developing safety measures because of the complexity in the international scenario. Safety assessment methods, development of guidelines, notification of necessary data for safety assessment and the extent of institutional mechanisms to perform the activities of risk analysis are a few of the challenges. In Brazil, the CNBS is authorised only to review the administrative appeal that is of national interest; in 2008, socioeconomic considerations were taken into account. But the CNBS powers are limited, as it cannot evaluate technical decisions

on GM traits and events approved by the CTNBio. Table 1 below represents the comparison of safety assessment and liability & redress components of National Food Safety Regulations of the BRICS countries.

**Table 1: Comparison of Components of Safety Assessment and Liability & Redress of BRICS Countries**

	Safety Assessment			Liability & Redress		
	Guiding Principles	Law	Enforcement Agency	Guiding Principles	Law	Enforcement Agency
<b>Brazil</b>	Precautionary, Science-Based Safety Assessment Techniques and Transparency	Normative Resolution No. 5 of 2008	SA Units under CTNBio <sup>e</sup>	No such issues on GM contamination. Liability principles are fault-based	Arts. 20 & 21 of Law No. 11,105 of 2005	CIBio
<b>Russia</b>	NIL	NIL	NIL	NIL	NIL	NIL
<b>India</b>	Substantial Equivalence, Science-Based Safety Assessment Techniques	Sec. 92(2) of FSSA <sup>a</sup> , 2006 & ICMR <sup>b</sup> Guidelines, 2008 (Updated 2012)	GMFSAU <sup>f</sup>	GM contamination is high. Principle of Liability towards GM food is not well established	Secs. 28 and 34 of FSSA, 2006	Food Business Operator
<b>China</b>	Generally Regarded As Safe, Science-Based Safety Assessment Techniques	Administrative Measures for Safety Evaluations of Agricultural GMOs	National Agricultural GMO Biosafety Committee	GM contamination is high. Liability fixed for applicant and Not Regulators	Food Safety Law 2009	Ministry of Agriculture
<b>South Africa</b>	Substantial Equivalence, Science-Based Safety Assessment Techniques	Codex Guidelines, Annexure III of CPB <sup>c</sup> , Regulation 4(5) & Sec. 5(c)(i) and Sec. 20(1) of GMO(A) Act <sup>d</sup> 2006+ Ministers shall make Regulations	Authorities established through the Act	GM contamination is high. Liability fixed for Regulators and Users. Liability imposed through consumer legislation	Secs. 5, 7 & 19 of GMO(A) Act 2006 and CPA 2008	User, Registrar, Executive Council

- a. Food Safety and Standards Authority of India
- b. Indian Council of Medical Research
- c. Cartagena Protocol on Biosafety
- d. Genetically Modified Organisms (Amendment) Act 2006 of South Africa
- e. Safety Assessment Units of National Technical Commission on Biosafety of Brazil
- f. Genetically Modified Food Safety Assessment Unit of India
- g. General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China
- h. Food Safety and Standards Act 2006 of India

### **5.2. Liability Mechanisms in BRICS Countries**

The GM Contamination Register provides instances of conventional crops being contaminated with GM food crops. For example, in 2013, 396 incidents of contamination by GM food crops across 63 countries were reported. Among these, the conventional variety of rice faced the highest amount of contamination, though there was no commercial cultivation of GM rice anywhere in the world market.<sup>61</sup> Bt-63 rice from China and LLRICE (Liberty Link Rice) from the United States showed high contamination with 35%, while maize showed 25% contamination, and soybean and rapeseed both about 10%.<sup>62</sup>

Several countries in Africa, and especially South Africa, have imposed a moratorium and enacted regulations to limit the use of grain derived from GMOs donated at the time of famine as food aid. Even though the population is facing difficulties with the scarcity of food, the regulators refused to import GM crops, considering the safety surrounding the foods.<sup>63</sup> The case of contamination is not only restricted to organic farmers and to the farm fields, it also extends to health effects on consumers. In *Gallagher v. Chipotle Mexican Grill Inc.* (2015), for instance a class action lawsuit was filed by a Californian woman before the United States District Court of Northern California claiming that the food served at a restaurant contained an ingredient of GM, whereas the advertisement was GM free.

In India, traces of cotton seed oil developed from Bt cotton seeds (first introduced in 2002), which were not approved for food use, nevertheless were discovered in human foods.<sup>64</sup> Furthermore, in most parts of India, canola oil imported from Canada is sold in supermarkets without any sensible labelling strategies. There might be the

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<sup>61</sup> Genetically Modified (GM) Rice, International Rice Research Institute (IRRI) (Feb. 20, 2018), available at <http://irri.org/news/hot-topics/genetically-modified-gm-rice>.

<sup>62</sup> Price & Cotter 2014.

<sup>63</sup> José Falck Zepeda, *Coexistence, Genetically Modified Biotechnologies and Biosafety: Implications for Developing Countries*, 88(5) *American Journal of Agricultural Economics* 1200 (2006).

<sup>64</sup> Committee on Agriculture, Cultivation of Genetically Modified Food Crops-Prospects and Effects, Ministry of Agriculture, India, 37<sup>th</sup> Report (2011–2012).

chance of contamination, because 74% of the canola cultivation in Canada is through genetically modified techniques. Therefore, contamination causes a significant threat at the time of import as well as at the time of domestic introduction. Moreover, in India, the country is interested in importing GM in the form of additives in the near future. In the process of the transboundary trade of GM foods, many parties could be involved as operators, which necessitates the importance of determination of liability.

Therefore, the question of legal liability for injury arising out of the import and the introduction of GM food emerges as a crucial issue confronting the promotion of GM food and derivatives.<sup>65</sup> In South Africa, liability has been dealt with in two aspects. The ultimate responsibility rested upon the consumer for any accidents involving GMOs before the establishment of the Genetically Modified Organisms Act 1997. Furthermore, the Genetically Modified Organisms (Amendment) Act 2006 plays a significant role in designing liability from the level of regulators to consumers. Liability has been fixed for each and every institution viz. the Executive Council, the registrar and the users concerned. In addition to the liability specified in the GMO Act, liability may arise in other consumer legislation, i.e. the Consumer Protection Act 2008. The producer, importer, distributor or a retailer whoever that may be is liable for any harm that is caused while supplying any unsafe goods, a product failure, defect or hazard in any goods, inadequate and false descriptions on labels, resulting in a loss to the consumer, including death and illness, loss in respect of personal damage or damage to property and economic loss, all of which shall be compensated as per the Consumer Protection Act, 2008.

Article 27 of the Cartagena Protocol on Biosafety was implemented in Arts. 20 and 21 of Law No. 11,105 of 2005 of Brazil with certain exceptions to it. The strict liability doctrine was opposed by the regulators of Brazil, and thus it was agreed to adopt a narrow definition of damage and a narrow definition of the operator. Article 20 of the Law contemplates that those who cause any damage to a third party or the environment while performing the activities concerning GM food and derivatives shall be liable for complete indemnification and reparation. In furtherance, Art. 21 contemplates that any actions or omissions that violate or negate the standards established by the Law shall be considered as administrative violations. In certain instances, CIBio is required to share information with the workers and other communities relating to accidents arising out of the introduction or import of GM food and derivatives.

In India, the current FSSA 2006 does not have any provisions to deal with response measures; rather, it provides food recall procedures in Sec. 28 of the Act. Through this provision, the food business operator is entitled to initiate procedures for withdrawal of marketing food if he believes that the food he has processed, manufactured

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<sup>65</sup> Shanmugam Kabaleeswaran Balashanmugam et al., *South Asian Perspective on Institutional Mechanism for Introduction and Import of GM Crops*, 35(2) *Biotechnology Law Report* 73 (2016).

or distributed is not in compliance with this Act. The operators shall exercise this provision only after informing consumers of the reasons for withdrawal. In addition to this provision, Sec. 34 of FSSA 2006 empowers designated officers to issue an emergency prohibition notice for imposing a prohibition against the health risk in respect of any food business. Therefore, the current FSSA 2006 does not have any appropriate procedure to deal with the damage caused by the transboundary trade of GM foods or remains silent on incorporating the procedures relating to emergency response measures.<sup>66</sup>

In China, in the case of any accidents during production or processing, the particular organisation involved in the activities concerning GM food shall be liable to take immediate actions. Furthermore, the information relating to the accident has to be communicated to the Administrative Department at the county level. In the case of illegal import, the food business operators shall be punished with a fine. Liability and redress mechanisms have been worked out to a limited extent in South Africa and to some extent in Brazil. But they are not well addressed in India and China. China, India and South Africa experienced the problem of contamination of GM food with the conventional counterpart. Currently, South Africa is interested in relaxing its stringent legislation on GMO and to start importing varieties of corn from the United States and Mexico. Previously, the storage or containment of GM food was not permitted at the ports of South Africa, whereas the Department of Agriculture has decided to allow storage at the ports during the transboundary movement in near future.

The main intention of temporal storage at ports is to encourage and enlarge the volume of GM imports from other nations.<sup>67</sup> While this is the actual situation, there might be a number of threats in relation to human health, animal health and the environment. The commercial cultivation of Bt brinjal has not been approved so far, but there are instances to show that there are transboundary concerns. For instance, there are reports alleging that the border districts of West Bengal (India) have been infiltrated with Bt brinjal seeds from Bangladesh. This brings to light the predicament of these countries on many counts. One aspect is that agricultural production needs to be increased with the support of GM technology. Another aspect is to ensure there are no risks posed in relation to people and the environment.

In the case of South Africa, the provisions relating to liability have been made available to both regulators as well as the applicants. But in the country, as in China, liability provisions have been fixed for the applicants and not the regulators.

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<sup>66</sup> Shanmugam Kabaleeswaran Balashanmugam et al., *Liability Aspects Related to Genetically Modified Food under the Food Safety Legislation in India*, 9(12) International Journal of Social, Behavioral, Educational, Economic, Business and Industrial Engineering 4060 (2015).

<sup>67</sup> Lorraine Chow, *Epic Drought and Food Crisis Prompts South Africa to Ease Restrictions on GMOs*, Eco Watch, 26 February 2016 (Feb. 20, 2018), available at <https://www.care2.com/causes/epic-drought-and-food-crisis-prompts-south-africa-to-ease-restrictions-on-gmos.html>.

While in India, the liability provisions are available to the regulators for dealing with conventional foods but not for GM foods. Furthermore, the 37<sup>th</sup> Report of the Committee of Agriculture also highlighted the importance of the liability clause in the form of claim, compensation for any adverse effects on the health of consumers, which needs to be established to address the emergence of GM food and derivatives in India. Contamination concerns in respect of GM foods is not only an issue for the countries engaged in GM cultivation or consumption; it is also an issue in other countries.<sup>68</sup>

In **Russia**, the question of legal liability for injury caused by GM food, right from the manufacturing phase to human consumption, emerges as a crucial issue confronting the promotion of GM food.<sup>69</sup>

In **South Africa**, liability has been dealt with in specific legislation. The ultimate responsibility to prove causation was on the consumer before the introduction of the Genetically Modified Organisms Act 1997. Currently, liability is determined for both regulators and consumers in the Genetically Modified Organisms (Amendment) Act 2006.

In the case of **Brazil**, the provisions in relation to civil liability and administrative liability concerning GM food and derivatives are incorporated in Arts. 20 and 21 of Law No. 11,105 of 2005 with certain exceptions (mentioned earlier). Article 20 of the Law contemplates that the offenders were ultimately liable in the form of indemnification and reparation for any damage caused to a third party or the environment. Furthermore, any actions or omissions that contravene the standards set down in the Law are administration violations and shall be punished by observing precautionary measures to seize the products, suspend the sale of the products and cancellation of the registration, license or authorisation.

In **China**, as mentioned earlier, the organisation involved in the production or processing of GM food shall be liable for any accidents (and responsible to take quick remedial action in accordance with Art. 5 N-KL Protocol on Liability and Redress).

In the case of **India**, the Indian Food Safety and Standards Act 2006 does not have any provisions to deal with response measures, but it does provide food recall procedures under Sec. 28 of the Act<sup>70</sup> as well as empowering designated officers to make public notice of emergency prohibitions, banning high-risk activities of any food business.

The varying standards and approaches towards dealing with damage is a major bottleneck in the development and realisation of an international civil liability system for GM foods. Moreover, the BRICS countries do not have a comprehensive liability

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<sup>68</sup> In the perspective of developing countries, China, India and South Africa are the top countries to adopt and commercialise GM crops. China and South Africa already are in the process of commercialising GM food crops, whereas India is willing to introduce GM food crops for commercialisation soon.

<sup>69</sup> Balashanmugam et al. 2015.

<sup>70</sup> *Nestle India Limited v. The Food Safety and Standards Authority of India and Ors.*, MANU/MH/1937/2015.

policy that applies to liability and damages arising out of the domestic introduction and import of GM food and derivatives.

After the thorough analysis on the development of the liability framework in the BRICS countries, the result is that the provisions available in the existing laws are not sufficient to deal with the damage, such as the long-term effects concerning the manufacturing to consumption of GM food and derivatives. The domestic legislation or the machinery in these countries does not address many crucial issues: the definition of damage, parties to the suit, determination of liability, proof of damage, exemption of liability and expiration of liability concerning suit for damages. Therefore, the situation requires either an amendment to the existing legislation or the incorporation of a specific liability law as in the case of the European Union to deal with the damage in relation to production and consumption of GM food and derivatives.

### **Conclusion**

The promotion of GM food crops in a large number of developing countries is a motivation to understand comparative aspects of adopted regulatory frameworks. Comparing and contrasting the legislation and regulations in the case of the BRICS countries reveals differences in their extent of development. Most BRICS countries lack appropriate procedures for safety assessment, and the institutional mechanism is not sufficient to perform the functions of safety evaluation and safety management. Some countries follow the safety methods recognised by the Codex Alimentarius Commission, whereas others the procedures given in Annexure III of the Cartagena Protocol on Biosafety.

The need to implement international agreements and to adhere to national policy considerations is not reconcilable. Further, transboundary considerations on GM crops necessitate that states choose among options: for example, whether to set down legal regulations to deal with transboundary trade in GM and, another, which path to take where existing legislation can be interpreted.

The development of an institutional mechanism for GM foods, compared to that of conventional foods, is still in the development stage in the BRICS countries. While more than two decades have passed since the introduction of GM food crops in some of the BRICS countries, transborder aspects such as the functions of the customs authorities have still not been addressed. This assumes importance in light of the reports of the rise in GM contamination. The differences in standards and approaches in dealing with damages are a concern in the international civil liability system.

As noted above, the merits, or otherwise, of such measures had political overtones in the past, but recent developments demonstrate that states have a broader scope to decide where to strike a balance between international commitments *vis-à-vis* national interest/public policy. This assumes importance due to the concept of

mutual recognition. It is imperative for states to begin to consider mutual recognition, considering the transboundary nature of GM crop products. At the same time, it is important that national regulators act in a socially responsible manner. Such determination is by regulations authorised by the domestic laws.

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