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REGULATING BIOSAFETY OF GENETICALLY MODIFIED CROPS IN INDONESIA: LIMITS AND CHALLENGES

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ABSTRACT

The global use of genetically modified (GM) crops is rapidly expanding. While the advent of this agricultural biotechnology offers new promises to cater to the rising demand for Indonesia's food security, the government should ensure its safety. This paper examined the regulatory regime over biosafety in Indonesia by considering the global fragmentation of biosafety regulation that debates its impact on environmental and health aspects. After Indonesia ratified the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, which specifically became the global guideline on how domestic biosafety policies are regulated, environmental and health issues are among the priorities that the use of GM crops contests to the precautionary approach. Amidst the insufficient scientific ground on its safety, GM crops use is supposed to result in adverse impacts, and the suspicion over the safety of such a new cutting-edge agricultural technology ended with a series of rejections. This paper's results

revealed that amongst the global contention over the regulatory regime on biosafety, which resulted in the bifurcation of biosafety regulation, Indonesia has added a new polarisation. This polarisation includes the release of GM crops certification, and Indonesia's desire of regulating biosafety deliberations over the definition and translation of biosafety in the domestic regulatory regime against the global regulatory diversity of biosafety.

Keywords: Biosafety, GM crops, precautionary principle.

INTRODUCTION

Most existing literature critically examined modern biotechnology through the appropriate regulatory regime of biosafety at the domestic level. The regulatory regime typically highlights the regulatory impact of bifurcation of the United States (US) and the European Union (EU) regarding the precautionary principle. As a consequence, this contention results in the polarisation of the regulatory regime in developing countries. However, the debate lacks critical discussion to include developing countries like Indonesia as part of the cornerstone to respond to the global regulatory framework on biosafety (Falkner & Gupta, 2009). This paper will consider the regulatory regime of biosafety for genetically modified (GM) crops in Indonesia. In particular, this paper will focus on the extent of Indonesia's efforts to implement the regulatory regime to meet environmental, food, and feed safety before GM crops are commercialised. Therefore, Indonesia's desire to regulate biosafety ultimately is deliberated over the definition and translation of biosafety in the domestic regulatory regime against the global regulatory diversity on biosafety.

Given that GM crops raise pros and cons worldwide, such as their contentions on scientific evidence and social perception against environmental, food, and feed safety, what is the motivation of the Indonesian government to eventually accommodate the regulatory framework of biosafety for GM crops? This paper will seek to answer this question by considering the precautionary principle as the underlying rationale for guiding policymakers to ensure that modern biotechnology can prevent adverse impacts on the environment and health. This study argues that by establishing the regulatory framework

for GM crops' assessment amidst the lack of scientific evidence to their safety, there are several options and challenges before reaching such a decision.

REGULATORY INQUIRIES ON BIOSAFETY IN INDONESIA

Technological advancement in agriculture has offered new cutting-edge biotechnological breakthroughs in facing the world's complex food security. Nevertheless, the use of modern biotechnology often requires the regulation of biosafety[1] and this effort has been an arduous task for governments in both industrialised and developing countries. At the outset, the regulatory regime has been commenced by the two competing approaches between the US and the EU to measure the level of risks that result from agricultural biotechnology. The US assumes that the justification for hazardous risks to the environment and human health should be scientifically proven (Falkner & Gupta, 2009). On the other hand, the EU strictly uses the precautionary approach, the commercial restriction under the ground of inadequate scientific assessment on the potential risk (Kelemen, 2010), to reject GM crops (Falkner & Gupta, 2009). This disagreement has politically and socially influenced other countries like Indonesia to regulate biosafety at the domestic level with pros and cons.

In short, the governments' attitudes in developing countries show an expectation to provide an alternative contributing to the alleviation of famine and poverty (Azadi & Ho, 2010). However, the uncertain safety of agricultural biotechnology results in the mistrust of the regulatory regime and suggests the rejection of the biosafety regulation (Ames, 2001) to protect biological diversity, including environmental protection and health safety.

Indeed, the green revolution has widely contributed to the alleviation of global hunger and poverty. The significant achievement has been

[1] The term biosafety refers to the safety of the use of modern biotechnology indicated with any technological innovation on the application of vitro nucleic acid techniques, including the recombinant DNA process in order to modify living organisms, biological systems or their derivatives for a specific use. See Article 2, the United Nations Convention on Biological Diversity and Article 3 Paragraph (i), Cartagena Protocol on Biosafety to the Convention on Biological Diversity.

revealed (Sands et al., 2009) deficiencies in certain amino acids, minerals, vitamins and fatty acids in staple crops, and animal diets derived from them, have aggravated the problem of malnutrition and the increasing incidence of certain chronic diseases in nominally well-nourished people (the so-called diseases of civilization; however, the recent trend shows the rise of world famine. The report by the Food and Agricultural Organization of the United Nations (FAO) concluded that there had been an increasing number of world hunger and undernourished people since 2014, with an estimate of 821 million people who did not receive enough food to eat in 2017 (Food and Agricultural Organization, 2018). Many scholars followed Amartya Sen's thesis that the shortage of food access is the very root of famine (Rubin, 2019). However, other analysts like Patrick Webb (Webb et al., 2006) criticised it due to the lack of conceptual clarity and the absence of a single perfect argument to address the multifaceted food insecurity over the food supply. In doing so, the 2009 World Summit on Food Security eventually recommended modern biotechnology in agriculture to increase agricultural productivity (Mechlem, 2010). These facts show a compelling need in response to the global demand of providing an alternative to the expansion of agricultural production, which results in the role of modern biotechnology becoming paramount. The desire to increase agricultural production, which is expected to contribute towards zero hunger as outlined in the Sustainable Development Goals (SDGs), can be an alternative.

Irrespective of the promise on the advantage and contribution arising from modern biotechnology, the following principal inquiry is around how to satisfy the biosafety regime to the existing biological conservation. The current debate on biosafety's regulatory regime primarily examines the standard to measure environmental safety and human health. Many leading countries in agricultural biotechnology like the US and the EU have continuously disputed it, particularly in dealing with the certainty of scientific evidence and the burden of proof on potential hazardous risks that result from agricultural biotechnology (Chowdhury & Sabhapandit, 2007). Emerging countries in agricultural biotechnology like South Africa (Ganpat et al., 2016) and Indonesia ("Indonesia Agriculture Ministry", 2013) have posed a similar trajectory despite a greater desire on the use and release of GM crops to meet food security and alleviate poverty (Zerbe, 2004; Azadi & Ho, 2010). Consequently, the present regulatory

regimes are substantially contested to environmental protection under the precautionary approach due to unknown risks resulting from the recombinant DNA process.

The underpinning argument over the precautionary approach broadly refers to Principle 15 of the Rio Declaration on Environment and Development. This Principle has become the primary guideline for policymakers to postpone any inventions when they face the lack of scientific certainty that potentially threatens human health and the environment. In particular, this Principle, which contains the precautionary principle, has been globally used for decision-making against environmental preservation where full scientific safety of new technology is still unknown. Such significance was subsequently accommodated in the Convention on Biological Diversity specialising in environmental protection, which laid the framework on the limits of exploration to modern biotechnology. This Convention considers potential damages of modern biotechnology to biological diversity and human health.[2] Each state is required to take appropriate measures on the use and release of modern biotechnology to meet environmental safety and human health[3] and allowed to postpone policies to prevent environmental degradation. It is clearly stated that the desire to use and release GM crops depends on the domestic regime and how it considers and translates the precautionary approach in order to anticipate potential risks arising from agricultural technology.

REVISITING EXISTING REGULATORY REGIMES ON BIOSAFETY

Since the ratification of the Convention on Biological Diversity (CBD) in 1994, Indonesia's regulatory framework of modern biotechnology and biosafety has been negotiated with the Convention. The ratification brought about the implementation of the Convention at the domestic level to meet appropriate procedures for safe transfer, handling, and use of any living modified organism resulting from modern biotechnology with the following potential adverse impacts.[4] In short, Indonesia's

[2] Article 8 (g), United Nations Convention on Biological Diversity.

[3] Article 19, United Nations Convention on Biological Diversity.

[4] Cartagena Protocol on Biosafety to the Convention on Biological Diversity.

desire to use biotechnology should meet the global guideline set in the Convention. This Convention requires the government to control potential hazardous risks to the environment and human health that result from biotechnology[5] and provide for effective participation in the development of biotechnological research before gaining the benefits arising from the results of genetic resources.[6]

Such ratification may assert the strategic role of Indonesia among the world's wealthiest countries in biodiversity. The Integrated Conservation and Development Programme (ICDP) reported that Indonesia is committed to protecting the current status as the world's second most biologically diverse nation (Wells, 1999). This ratification might eventually impede the country to formulate the regulatory regime on biosafety because many leading countries in agricultural biotechnology avoid the Convention's ratification, which seems to restrict its technological development. For example, the US uses GM crops in its primary agricultural production, which inspires Indonesia to develop a similar direction for agricultural biotechnology. However, the former nation has been reluctant to ratify the Convention (Blomquist, 2002). The US government's attitude is strongly motivated by the interests to protect its farmers for economic gains (Bang, 2011). Accordingly, the US experience appears to be irrelevant as an example for Indonesia, and it is suggested to exclude the US experience from the discussion.

These facts portray that regulating the appropriate regime of biosafety in Indonesia has become an arduous task for its government. This effort should answer how Indonesia's policymakers can negotiate the Convention on Biological Diversity, which prohibits the ill-defined regulatory regime from potential adverse damages. On the other hand, the potential adverse risk arising from agricultural biotechnology is still uncompromised globally. Therefore, as a representative of major developing countries in agricultural biotechnology, Indonesia has a more significant challenge to negotiate the regulatory regime on biosafety to meet the provisions in the Convention in order to avoid the contradiction of the existing legal regime. It heavily draws attention as to whether Indonesia's regulatory regime will successfully match both subjects with conflicting arguments.

[5] Article 8 (g), United Nations Convention on Biological Diversity.
[6] Article 19, United Nations Convention on Biological Diversity.

Historically, it was no more than two years after the Convention's ratification that Indonesia included research and development on modern biotechnology in Food Law No. 7 of 1996. This law accommodated food production resulting from genetic engineering to pass food security verification before commercialisation. As a result, the government must provide minimum standards of research and development of genetic engineering in food production, including the requirements on food examination.[7] However, in the beginning, there was no further significant policy taken by the government instead of the discussion over food safety following this new proposed technology. It was reflected in the insufficient food safety regime due to Indonesia's poor experience to address food safety issues.

Nevertheless, the government made a licence over the release of non-food crops like Bt cotton (Bahagiawati & Sutrisno, 2007), which lasted with the judicial proceedings. In 2001, the government licence was released to plant Bt cotton for seven regencies in South Sulawesi, i.e. Bantaeng, Bulukumba, Bone, Soppeng, Wajo, Gowa, and Takalar (Bahagiawati & Sutrisno, 2007). The process did not require a long time because it was not part of food or feed product. Instead, it considered the potential adverse impacts on the environment, biological diversity, and human health. This project aimed to generate high production in cotton. Pest-resistant transgenic crops were provided with improved fibres and limited only to these seven regencies under the government's evaluation and supervision. Under a two-year supervision, the release of Bt cotton met environmental safety measures and generated higher productivity, which resulted in economic gains to cotton farmers in South Sulawesi (Estiati & Herman, 2016). However, there was no clear reason why it was not sustained. It was indicated with the corporation's unpromising prospects to continue this project (Bahagiawati & Sutrisno, 2007). In the Constitutional Court's judgment, there was no adequate information and knowledge given to farmers on using these GM crops with their following potential adverse impacts.[8] This fact indicated a lack of evaluation process from the government regarding consumer protection so that farmers were unable to identify GM crops. In the end, the petition was filed to the Administrative Court by the coalition of several non-governmental organisations (NGOs), which are the Indonesian Center for Environmental Law,

[7] Article 12, Law No. 7 of 1996 on Food.

[8] The Constitutional Court, Decision No. 98/PUU-XI/2013, on the review of Food Law No. 18 of 2012, dated 15 September 2014, at 57.

the Indonesian Consumers Foundation, and the Consortium for the Indonesian Forest Conservation. The Appellate Court dismissed the appeal against transgenic cotton[9] with the following same attitude of the subsequent proceedings in the High Court[10] and the Supreme Court.[11] The courts focused on the actual rather than the potential adverse impacts resulted from the cutting-edge biotechnology's unknown risks, whereas environmental risk assessment could help to justify the possible unknown risks to the environment and health.

These situations show that the Indonesian government has started to implement the regulatory framework for adopting modern biotechnology. This step accounts that the government prioritised non-food commodities due to the consequence of human health, while the international law provided a limited global guideline on biosafety. In particular, the Convention on Biological Diversity only sets general provisions on how biosafety is regulated but no adequate provisions on how the standard is applied. Therefore, the Convention still lacks further elaboration on the procedure and application of biosafety in the domestic regulatory regime until the Cartagena Protocol on Biosafety was adopted in 2000.

The Cartagena Protocol contributed to a significant establishment of the regulatory regime on biosafety in Indonesia. After the ratification of the Protocol in 2004, Indonesia's regulatory regime laid the firm step by adopting the framework of biosafety set in the Protocol, which explores the precautionary approach entrenched in the Rio Declaration.[12] The Protocol heavily emphasises the basic provisions on advance informed agreements, the procedure of utilisation against GM crops, risk assessment, cross-border transfer under emergency measures, biosafety clearing-house, capacity building, and parties' social duties. As a result, several government and ministerial regulations in Indonesia govern the procedure on biosafety, including the establishment of the Biosafety Clearing-House (BCH).

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9 The Administrative Appellate Court, Decision No. 71/G.TYN/2001/PTUN.JKT, dated 27 September 2001.

10 The Administrative High Court, Decision No. 16/B/2002/PT.TUN.JKT, dated 12 March 2002.

11 The Supreme Court Decision, No. 336K/TUN/2002, dated on 31 August 2004.

12 Article 1, Cartagena Protocol on Biosafety to the Convention on Biological Diversity

This approach asserts the government's essential motivation on how research and development take a considerable role in ensuring biotechnology. It also shows the anticipation of global competition by considering GM crops as an alternative. In fact, using agricultural biotechnology is the most common attitude of Asian countries, such as China, India, and Indonesia, to plant millions of acres of GM cotton (Barboza, 2003).

On the other hand, the formulation of a regulatory system on biosafety is not easy, as it resulted in consumers' fear and mistrust of biosafety regulation. Therefore, the debate over the safety of transgenic crops led to serious trade disputes in terms of biosafety issues and precautionary approaches. For instance, the dispute between the EU and the US over Bt corn varieties and herbicide-resistant soybeans (Ames, 2001). This dispute started in 1998 after the EU postponed the import of biotechnology products under the ground of scientific analysis (Ames, 2001). It was followed by consumers who prefer conventional crops. Simultaneously, NGOs like Greenpeace and Friends of the Earth underlined the government statement's precautionary approach and warned further damage to traditional crops (Ames, 2001).

Following these competing facts, the formulation of biosafety in Indonesia has undergone an arduous task. In 1999, the joint ministerial decrees on biosafety and food safety of agricultural products resulted from genetic engineering were unveiled.[13] Such joint decrees addressed the condition and appropriate measures to avoid agricultural products of agricultural engineering from the potential adverse impacts against biological diversity, including animals, fishes, plants, and the environment. Therefore, the Commission on Food and Biosafety was established against food, plants, animals, fishes, and microorganisms.

In 2004, the Government Regulation No. 28 of 2004 on Safety, Quality, and Nutrition of Food was passed to regulate GM crops utilisation. In the following year, the aforementioned joint ministerial decrees enacted in 1999 were re-enacted in the Government Regulation No. 21 of 2005 on Biosafety of Genetically Engineering Products. In this

[13] They were Joint Decrees of the Ministry of Agriculture, Ministry of Forestry and Plantation, Ministry of Health, and Ministry of Food and Horticulture No. 998.1/Kpts/OT.210/9/99; 790.a/Kpts- IX/1999 and No. 1145A/MENKES/SKB/IX/99; 015A/ NmenegPHOR/09/1999

regulation, the biosafety of genetic engineering mainly aims to protect environmental, food, and feed safety. It also optimises the production resulting from genetically modified organisms (GMOs) based on health principles, biological diversity, consumer protection, legal, and business certainty.[14] To meet this aim, the regulation is classified into the types and requirements, research and development, importation, assessment, release, circulation, and utilisation of GMOs despite supervision.

The government's attitude towards adopting modern biotechnology is reflected in the revised Food Law No. 18 of 2012. In Article 77, this law governs food production prohibition resulting from agricultural biotechnology without any approval of food safety. This reflects the importance of biosafety regulation to pass food safety. This law highlights the procedure of BCH to assess potential risks resulted from agricultural biotechnology before commercialisation. However, this provision was challenged in the Constitutional Court by a coalition of NGOs that included the Indonesian Farmers Alliance, the Consortium of Indonesian Farmers, and the Indonesian Forum for Environment. They appealed to annul the provision to the approval of GM crops.[15] These NGOs rejected the use and commercialisation of GM crops in the country. The Court considered the use of new technology to anticipate climate change against food supply, and such technology is expected to bring economic gains for farmers as experienced in other countries.[16] In doing so, the Court suggested adopting the comprehensive biosafety framework before releasing GM food crops to protect citizens, ensuring adequate access to food. This decision asserts that GM crops play a key role in Indonesia's food security. In 2005, the data accounted that the country imported transgenic soybeans from the US and Argentina up to 90 percent of the total consumption due to the insufficient supply from domestic production (Bahagiawati & Sutrisno, 2007). Indonesia also imported transgenic corns to provide food and feed supply up to 43 percent of the total consumption to meet the drastic increasing demand (Bahagiawati & Sutrisno, 2007). With the following licences for transgenic crops, the

[14] Article 2, Government Regulation No. 21 of 2005 on Biosafety of Genetically Engineering Products.

[15] The Constitutional Court, Decision No. 98/PUU-XI/2013, on the review of Food Law No. 18 of 2012, dated 15 September 2014, at 57.

[16] *Id*. at 99.

complex regulation increases bureaucratic procedure on biosafety evaluation. Indeed, this attitude affirms the initiative to provide a comprehensive framework on biosafety, for instance, by adding the requirements for an environmental impact assessment on every activity using genetic engineering products. Such complexities show the multifaceted biosafety evaluation layers, which was not supported by an efficient regulatory system.

After ratifying the Cartagena Protocol, the Indonesian government eventually took a firm step to maximise the BCH role and replace other commissions that grant the power for biosafety assessment. However, the regulatory system does not cover the provision to ensure biosafety evaluation against imported transgenic food products such as products from the US and Argentina. In general, Article 6 paragraph (1) of the Government Regulation on Biosafety of Genetically Engineering Products requires all GM products from Indonesia and abroad to be examined by providing information of products that have met the environmental, food, and feed safety measures. Nevertheless, the emphasis of this regulation is limited to administrative requirements.[17] Therefore, there is a paradox where the focus of the regulatory system was the registration of new transgenic crops developed in Indonesia rather than to ensure all consumed products either planted or imported into Indonesia to be included in the biosafety evaluation.

[17] In order to meet environmental safety, the necessary information includes the description and the objective of the product use, the detection of genetic and phenotype changes, the identity on the taxonomy, physiology, and reproduction of genetically engineered products, organism identity, the method of genetic engineering, molecular characterisation of genetically engineered products, the stability of genetical expression, and the method of destruction from potential deviation. See Article 6 paragraph (2), the Government Regulation on Biosafety of Genetically Engineering Products. Besides, to meet food and feed safety, the information includes the method, nutrient content, toxic compound, anti-nutrition, and allergens. It should also include carbohydrate, protein, ash, fat, fibre, amino acids, fatty acids, minerals, and vitamins in the GM products, which must be substantially commensurate with non-GM products, non-allergen proteins encoded by the transferred gene, and the method of destruction used when there is a deviation to products. See Article 6 paragraph (3), the Government Regulation on Biosafety of Genetically Engineering Products.

DEFINING THE PRECAUTIONARY PRINCIPLE IN INDONESIA

One of the central debates over the use of biotechnology is to the extent that this new cutting-edge technology is contested and negotiated to meet biosafety, which includes the precautionary principle of international environmental law as its core element. Analysts like Treich (2001) have reflected that the principle is used to answer the society's response to potential hazards whose qualities are unknown. Therefore, the operationalisation of the Cartagena Protocol on Biosafety needs to settle the contentious meaning over the precautionary principle, referred to as the regulatory regime on transgenic crops globally. There is no general agreement to the definition of the precautionary principle and how to apply it in different social, economic, and cultural systems.[18] Considering the principle is implanted from international law, it results in different perceptions of interpreting and translating the principle in domestic laws. Therefore, the disagreement is inevitable to the various interpretations of the principle to articulate science-based precaution in compliance with food safety, environmental risks, and social issues despite the economic interests. The rejection of the EU to the GM crops is evident in that it affects agricultural biotechnology in the US and led to the uneasy trade dispute at the World Trade Organization (WTO), to the extent that it examined the science-based safety.

As a result of domestic autonomy to define the precautionary approach, this approach's interpretation reflects a global confusion rather than merely a choice. On the one hand, states are called for preventing potential adverse risks that result from modern biotechnology. On the other hand, due to the absence of international standards to justify possible hazardous risks and the unclear meaning of the precautionary approach, the decision to measure such potential damages is vested to each state. Therefore, each state that desires to use GM crops plays a vital role in negotiating both environmental safety and modern biotechnology in the domestic regulatory regime.

[18] Report of the Conference on Science and the Precautionary Principle, 2000.

A. Defining the Precautionary Principle

In general, the precautionary principle emerges as an international standard applied to a legal mechanism for anticipating environmental risks by considering insufficient scientific knowledge of newly-adopted technology. It arises from the criticism of the current new technology based on scientific findings. The underlying reason for introducing the principle is that certain human activities potentially result in both positive and negative impacts on the environment and human health (Chowdhury & Sabhapandit, 2007)this does not take away the fact that the precautionary principle continues to be applied widely across sectors both internationally and nationally. The nature and scope of its application has varied widely according to the context and sector within which it has been applied. The central issue which this article seeks to address is the regulatory and the policy making space that is available to the Government of India in the context of the obligations as undertaken under the Cartagena Protocol and under various other international treaties. The regulatory space would also be affected by the domestic legal developments across sectors in which the principle has been applied. India's recent decision on the large-scale commercialisation of Bt-Cotton has already created much debate regarding its appropriateness given the realities of Indian farm practices. More specifically, it has also led to a rethinking of the role and application of the precautionary principle in addressing these realities. Considering that the Indian policy on biotechnology is currently being drafted, it is important to look into the scope of applying the precautionary principle in taking any decision on genetically modified organisms (GMO. The principle emphasises the disallowance of proposed activities carried by the new technology with its potential environmental risk. Moreover, it follows the basic premise due to the lack of scientific prediction of the adverse outcome in driving 'the better safe than sorry' policy approach (Puttagunta, 2001). Therefore, the following interpretation principle plays a vital role in safety consideration once new technological innovation is commercialised.

Historically, the precautionary principle was rooted in Germany's domestic regime in the 1960s (Chowdhury & Sabhapandit, 2007) this does not take away the fact that the precautionary principle continues to be applied widely across sectors both internationally and

nationally. The nature and scope of its application has varied widely according to the context and sector within which it has been applied. The central issue which this article seeks to address is the regulatory and the policy making space that is available to the Government of India in the context of the obligations as undertaken under the Cartagena Protocol and under various other international treaties. The regulatory space would also be affected by the domestic legal developments across sectors in which the principle has been applied. India's recent decision on the large-scale commercialisation of Bt-Cotton has already created much debate regarding its appropriateness given the realities of Indian farm practices. More specifically, it has also led to a rethinking of the role and application of the precautionary principle in addressing these realities. Considering that the Indian policy on biotechnology is currently being drafted, it is important to look into the scope of applying the precautionary principle in taking any decision on genetically modified organisms (GMO. It aimed to promote socialised planning with participatory measures and strong moral requirements to avoid harm and stimulate the economy through green alternatives (Puttagunta, 2001). The principle has subsequently developed in the European Commission and has been adopted into the treaty establishing the EU with the following elaboration to implement comprehensive risk assessment procedures (Weiss, 2003). The Maastricht Treaty and Amsterdam Treaty acknowledge applying the precautionary principle as the guideline for policymakers to protect environmental safety (Chowdhury & Sabhapandit, 2007)this does not take away the fact that the precautionary principle continues to be applied widely across sectors both internationally and nationally. The nature and scope of its application has varied widely according to the context and sector within which it has been applied. The central issue which this article seeks to address is the regulatory and the policy making space that is available to the Government of India in the context of the obligations as undertaken under the Cartagena Protocol and under various other international treaties. The regulatory space would also be affected by the domestic legal developments across sectors in which the principle has been applied. India's recent decision on the large-scale commercialisation of Bt-Cotton has already created much debate regarding its appropriateness given the realities of Indian farm practices. More specifically, it has also led to a rethinking of the role and application of the precautionary principle in addressing these realities. Considering that the Indian policy on

biotechnology is currently being drafted, it is important to look into the scope of applying the precautionary principle in taking any decision on genetically modified organisms (GMO. The importance of such science-based precaution is also enshrined in Article 7 of the General Food Law stating, "[I]n specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified, but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment".

It is essential to note that the principle also appeared before the term precautionary principle was introduced globally. It was applied to the use of potentially carcinogenic food additive in the US. Delaney Clause of the Federal Food, Drug, and Cosmetic (FDC) Act (Sandin, 2006). The Clause comprises provisions on food additives, colour additives, and animal drug residues as a means to control and minimise human activities and protect public health, with the consideration that any chemical materials in laboratory experiments often cause cancer (Picut & Parker, 1992). Though the context was not intended for the use of biotechnology, the very reason to apply the precautionary principle in the US, according to the FDC Act, was essential to protect human health against hazardous risks (Sandin, 2006).

In contrast, there have been several opposing arguments to the precautionary principle indicated with the ill-defined principle due to the absence of a clear and proper legal definition (Sandin, 2006). It resulted in the interpretation's flexibility that places the principle as a legitimate tool to ban any products that are assumed to bring human health and environmental risks. As a result, unscientific applications place science into a marginalised role in the decision–making process. There is no adverse impact reported in the peer-review academic article (Eggers & Mackenzie, 2000) in response to the fear of GM crops that is claimed to bring catastrophic risks to human health and the environment. Consequently, there is uncertainty regarding the conflicting arguments over the precautionary principle from academia, particularly against the degree of consistency with the following burden of proof (Chowdhury & Sabhapandit, 2007)this does not take away the fact that the precautionary principle continues to be applied

widely across sectors both internationally and nationally. The nature and scope of its application has varied widely according to the context and sector within which it has been applied. The central issue which this article seeks to address is the regulatory and the policy making space that is available to the Government of India in the context of the obligations as undertaken under the Cartagena Protocol and under various other international treaties. The regulatory space would also be affected by the domestic legal developments across sectors in which the principle has been applied. India's recent decision on the large-scale commercialisation of Bt-Cotton has already created much debate regarding its appropriateness given the realities of Indian farm practices. More specifically, it has also led to a rethinking of the role and application of the precautionary principle in addressing these realities. Considering that the Indian policy on biotechnology is currently being drafted, it is important to look into the scope of applying the precautionary principle in taking any decision on genetically modified organisms (GMO. Eventually, this uncertainty resulted in the public's scepticism against governments to formulate policies on modern biotechnology and biosafety to promote their domestic prosperity or alleviate poverty. In particular, such scepticism is heavily regarded when confronted with food safety issues.

As a result, there has been a global restriction to plant GM food crops. For example, countries in Central and Latin America prohibit GM food crops, South Africa only allows the planting of white maize GM seeds in a limited number, the Philippines only allows the planting of sweetcorn GM, Bangladesh restricts the planting of eggplant GM crops only, and China does the same to cotton only (Paarlberg, 2014, p. 224). Indonesia permits corn and sugarcane GM crops only (BCH, 2018). On the other hand, the use of specific genetic characteristics of GM crops promises productivity gains. In particular, the benefit is expected to overcome problems in developing countries that rely on high food production in alleviating hunger and poverty. The significant role of modern biotechnology is preoccupied with the Global Hunger Index in 2018, which shows z high level of hunger index in developing countries. For instance, Indonesia ranked 73rd out of 119 participating countries with 21.9, asserting the country is at a dangerous level of hunger, while South Africa, the Philippines, and Bangladesh ranked 60th, 69^{th,} and 86th, respectively (Global Hunger Index, 2018). The contentious meaning over the precautionary principle has heavily

influenced the need to provide adequate food due to the regulatory regime on biosafety that considers adverse risks on the environment and human health.

B. Defining the Precautionary Principle in Indonesia

In Indonesia, the precautionary principle has recently added a new debate over environmental protection. This principle previously resulted in difficulties for judges and policymakers to adopt and implement it amidst the lack of discussion on whether the principle can be applied to any new technology that could possibly threaten the environment (Wibisana, 2011).[19] This also included the applicability of the principle outlined in the Rio Declaration on Environment and Development, whether this is a soft or hard law to adopt in Indonesia regarding all environmental cases (Wibisana, 2011). This emerging concept emphasises the insufficient provisions in response to new technological advancements that substantially refer to the precautionary principle's aim in protecting the environment.

The debate over the principle has re-emerged after the 1992 CBD was introduced. After Indonesia ratified the CBD in 1994, this principle was shortly introduced in Law No. 23 of 1997 on the Environmental Management Act. Then, Law No. 32 of 2009 on Environmental Protection and Management replaced Law No. 23 of 1997. Article 47 of Law No. 23 of 1997 requires an environmental risk analysis regarding activities that potentially result in adverse impacts and threats on the environment, ecosystem, health, and human safety. In particular, this kind of environmental risk analysis is a paramount procedure in studying the release and distribution of GMO products. To be sure, in the transgenic cotton case that is appealed in the courts, judges must consider this provision as the basis to hinder potential harms resulting from modern biotechnology. Understanding the precautionary approach has become essential as to how judges apply and interpret laws to ensure sustainable development.

[19] An attempt to recognise the precautionary principle was first under the *Kapas Transgenik* (transgenic cotton) case. Environmental NGOs submitted the lawsuit in 2001, which appealed to the Administrative Court to nullify the Minister's permit that licensed the release of transgenic cotton produced by Monagro Kimia, an Indonesian subsidiary of Monsanto.

The precautionary principle is reiterated in the Government Regulation No. 21 of 2015 on Biosafety of Genetically Engineering Products. Article 3 of this regulation states the significance of the precautionary approach to meet environmental, food, and feed safety using scientific methods by considering the religious norm, ethics, social and cultural aspects, and aesthetics. This article has clearly provided the juridical ground on adopting the precautionary principle in Indonesia's biosafety policy. This article adopts Principle 12 of the 1992 Rio Declaration on the government measures' postponement under the reason of insufficient full scientific certainty to avoid environmental degradation.

In this context, such a precautionary approach is applied in the research and development with the requirement to anticipate and prevent adverse risks to human health[20] before objects are released and commercialised. Though the primary obligation to research and develop GMOs is upon the government, the society is involved as well to gain the domestic GMOs in which they will be given compensation as it refers to national interests.[21]

CONCLUSION

Globally, the use of GM crops as part of agricultural biotechnology remains controversial. There is no global consensus on the crops and activities covered, including mandatory pre-market approval and established safety standards for domestic legislation. For instance, the US takes on the framework that heavily emphasises environmental rather than food safety issues, followed by other countries like South Africa and Argentina. In contrast, the EU has a more restrictive policy by accommodating environmental and food aspects in all regulatory regime components. The interpretation of the precautionary principle has significantly contributed to justifying the domestic regulatory regime. Amidst the global bifurcation on GM products, Indonesia tries to use GM crops in favour of an agrarian country that wants to expand food production to meet food security. In doing so, the

[20] Article 6, Government Regulation No. 21 of 2005 on Biosafety of Genetically Engineering Products.

[21] Article 11, Government Regulation No. 21 of 2005 on Biosafety of Genetically Engineering Products.

government has started to implement the regulatory framework on modern biotechnology and biosafety. GM crops can be an option for Indonesia's food security; nevertheless, the lack of scientific ground regarding their safety will be a long-term debate for Indonesia to negotiate with further scientific issues. With the absence of sufficient parameters to define the precautionary principle in the domestic regulatory regime, Indonesia has equivocally defined it. This incomprehensive definition has tended to follow the US's regulatory model that widely accepts GM crops.

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