

## Legal Aspects of Genetically Modified Food Product Safety for Health in Indonesia

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### **Abstract**

*Genetic Engineering is the transplantation of one gene to another, both between genes and across genes, to produce valuable products for living beings. The rapid growth of genetic engineering in Indonesia and Genetically Modified (GM) food products has raised many worries and issues about these foods posing a health risk when consumed. Concerns about GM food products are increasing, including the possibility of allergic reactions, gene transfer, and outcrossing. Indonesia is one of the countries that has accepted the Cartagena Protocol, a security protocol designed to protect biodiversity from the potential risk posed by genetically modified organisms created by contemporary biotechnology. The writer, through this study, would like to convey the extent to which the existing regulations in Indonesia regarding GM food product safety for public health and how the government's responsibility in GM food product safety is for public health. As a result of this study, GM food products had been regulated by law, and the establishment of a Biosafety Commission was one form of government responsibility for preserving the safety of GM food products for public health.*

**Keywords:** food, genetic engineering, cartagena protocol

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### **Introduction**

Technology in the food supply has developed rapidly, especially in developed countries, such as the United States, Canada, England, Australia, etc. The research discovered a breakthrough in the form of Genetically Modified Organisms (GMOs), which may be utilized to solve the problem of food shortages swiftly, but there are still safety concerns. Internationally, the European Union and international organizations such as the Codex Alimentarius Commission (CAC) play a significant role in raising concerns about the consumption of Genetically Modified (GM) foods and the need for labelling and regulation of GM products (FAO, 2001). CAC is an intergovernmental organization founded by the Food and Agricultural Organization (FAO) and the World Health Organization (WHO) with 163 countries members.<sup>1</sup>

Traditional and modern biotechnology are the two types of biotechnology. Traditional biotechnology is the use of microorganisms (organisms) to alter materials and the environment in order to get optimal results. The making process of Tempe (fermented soybean cake), Tape (fermented cassava) and bread are examples of traditional biotechnology. Meanwhile, modern biotechnology employs human abilities to manipulate biological organisms to create the desired result, such as through genetic engineering procedures.<sup>2</sup> Genetic Engineering is the transplantation of one gene to another, both between genes and across genes, to produce useful for living things. Initially, genetic Engineering was used to produce ideal creatures; for example, tomatoes that could not be grown in low-temperature locations were designed to become frost-resistant plants with a longer growing season and the ability to be cultivated in any weather.<sup>3</sup> It is only done on plants to solve the problem of food shortages, and in its development, genetic engineering is used for plants and animals and has also evolved in humans. It is also commonly utilized in agricultural food technologies to increase production and quality and post-harvest improvements. Biotechnological plants authorized for use in food are modified to have traits such as (1) pest and disease resistance, (2) herbicide resistance, (3) nutritional content engineering, and (4) improved shelf life (Manuhara, 2006).<sup>4</sup>

Controversy over genetically modified products (from now on abbreviated as GM products) is still happening today. Several worldwide challenges have surfaced, including the dangers of genetically engineered foods for health. In 1996, WHO discovered a new type of chemical contained in transgenic organisms and their products. These chemicals resulted in new illnesses, such as the AAD gene, which was discovered in transgenic cotton and may be passed on to bacteria that cause gonorrhea.<sup>5</sup> GM product continues to bring up pros and cons in the community. According to agreed people, GM products can be useful in reducing the use of plant chemicals, overcoming food shortages, and being able to produce good quality food, yet, on the other hand, the disagreed people see the safety of GM products cannot be proven for consumption since it is thought to have a detrimental impact on health when ingested, as well as a destructive impact on the environment and the inability to improve lucrative yields.<sup>6</sup>

Imported genetically modified crops currently circulating in Indonesia include soybeans, corn, and potatoes. Most of the population in Indonesia daily consume Tempe (fermented soybean cake) and tofu as vegetable side dishes. According to Young and Lewis (1995), there was very little information on the effects of changes in the nutritional composition of GMO (Genetically Modified Organisms) foods from both plants and animals, such as nutrient interactions, gene interactions, bioavailability/absorption of nutrients, potency nutrition, nutrient metabolism, and gene expression in situations in which nutrients are altered.<sup>7</sup> Based on this information, it is suspected that there is no single study that guarantees genetically modified food is 100% safe for consumption. According to Dresbach et al., not all of the effects of GMOs have been examined. Thus there is no certainty about their safety.<sup>8</sup> Based on the above description, and the writers want to investigate the legal regulation of the safety of GM products for health in Indonesia and the government's responsibilities to the people who consume GM products.

### Research Method

There are five approaches in legal research, namely: the statute approach, the case approach, the historical approach, the comparative approach, and the conceptual approach. This research is normative in nature by taking a statute approach, which examines all laws and regulations related to the legal issues being handled (Peter Mahmud Marzuki, 2016:133), and a conceptual approach (conceptual approach) that moves from the views and doctrines that develop in the science of law, so that researchers will find ideas that give birth to understandings that are relevant to the legal issues faced (Peter Mahmud Marzuki, 2016: 133).

### Analysis and Discussion

#### A. Legal regulation of genetically modified (GM) food products in Indonesia

Genetic Engineering of living things, whether in plants, animals, or people, generates moral debate among scientists and legal controversy.<sup>9</sup> The United States, the European Union, China, Africa, Australia, and the Philippines have regulated the circulation of GM food products. According to the Biosafety Clearing-House database, food safety has been declared for 117 Genetically-Modified Corn, 33 Genetically-Modified soybeans, and 99 Genetically-Modified potatoes. Meanwhile, based on the Center for Environmental Risk Assessment database, currently, there are around 184 types of GMO declared as safe food.<sup>10</sup>

The government regulates the safety of genetically modified food products, referring to the results of the convention on biodiversity in the world. The Cartagena Protocol, an agreement between various parties that regulates the procedures for deliberate cross-border movement, including the handling and utilization of a living organism produced by modern biotechnology from one country to another by a person or entity, has been ratified by the Indonesian government.<sup>11</sup> The Cartagena Protocol is a further implementation of the Convention on Biological Diversity (Protocol Cartagena on Biosafety) which aims to ensure a level of protection in the safe transfer, handling and use of genetically modified organisms (GMO). GMO food products such as corn, soybeans, and potatoes are extensively distributed in Indonesia. Thus, the government must anticipate it, particularly those that threaten biodiversity and human health, by ratifying the Cartagena Protocol into Law No. 21 of 2004 on Ratification of the Cartagena Protocol on Biosafety to The Convention On Biological Diversity (from now on referred to as the Cartagena Protocol Law). Article 11 paragraph (1) of the Cartagena protocol states that the party making the final decision regarding domestic use within fifteen days after the decision is made must notify the parties through the Indonesia Biosafety Clearing House. The party shall submit a written copy of the material to the National Focal Point of each party, indicating that it does not have access to the Biosafety Clearing House in advance.<sup>12</sup> One of the Cartagena Protocol Law functions is to obtain optimal benefits from the safe use of modern biotechnology without harming biodiversity and human health.

According to Law No. 36 of 2009 on Health (from now on referred to as the Health Law) Article 109, anyone who distributes GMO products must guarantee their safety for the community or consumers and the surrounding environment. Meanwhile, based on Article 77 paragraph (1) of Law No. 8 of 2012 on Food (from now on referred to as the Food Law), there is a government authority in charge of issuing a permit from the GMO produced to regulate its circulation in public. Then Article 78 paragraph (1) explains that those who develop GMO products must adhere to the government's

guidelines to ensure the product's quality to be assured and safe for the general public consumption. For those who violate the provisions of the requirements set by the government, administrative consequences in the form of fines, temporary stoppage of operations, production, and circulation, withdrawal of food from circulation by producers, compensation, and license revocation will be imposed, as specified in Article 79.

As referred to as in Government Regulation No. 28 of 2004 on Food Safety, Quality and Nutrition Article 14 paragraph (2), the safety checks for GM food products must include genetic information, description of donor organisms, description of genetic Engineering, characterization of genetic Engineering, and information on food safety.

Government Regulation No. 69 of 1999 on food labelling and marketing was established by the government in order for the people to know whether the food they eat is the result of genetic engineering or not. According to Article 35 of Government Regulation No. 69 of 1999, GMO food must have a genetically modified food label, information on GMO food and a distinctive logo arising from genetic engineering.

The requirement to include information on genetically modified foods is informative because, in general, food products circulating in the market are safe products for consumption, free of harmful ingredients and processed well to ensure their safety.

Supervision and control of GMO food products are regulated in Article 25 of Government Regulation No. 21 of 2005 on the biosafety of Genetically Modified Product. Supervision and control of PRG products are carried out by the Minister or the authorized Head of LPND. After the Minister or head of the LPND receives the report, they will assign the Biosafety Commission to check the truth of the report. If the GMF product is found to have a harmful impact on health or the environment, the relevant Minister has the authority to cancel the GMF product's circulation.

#### **B. Government responsibility for the safety of genetically modified food (GMF) products for health.**

On the other hand, health insurance for GMO products such as soybeans is not yet guaranteed. One of the experts in genetic engineering, Jeffrey M. Smith in Seeds of Deception and Genetic Roulette, said there are at least 65 serious health risks due to consuming GMF products. In fact, according to Smith, between 1994-2001, there was a phenomenon where food-related diseases had doubled along with the circulating GMF products. According to Mae Wan Ho, genetically modified plants are useless and harmful to health.<sup>14</sup> The issue of food safety, including genetically modified food, has become a concern in several developed countries such as Australia, New Zealand, and several European countries.

Some countries are trying their best to protect their citizens from minimizing the impact of GMF products. However, it is not the case in developing countries like Indonesia, which focus solely on food sufficiency and not on food security. While developing countries have not been able to ensure the safety of food products in the form of agricultural commodities, the state must still ensure information disclosure and security.

Genetically modified food is derived from genetically modified living things. In general, food is sourced from plants; currently, genetic engineering in plants is being developed. GMO plants are widely used as food ingredients which are commonly

known as genetically modified food products. The usage of MGO products raises worries and issues that these foods may pose a health risk when consumed, including the possibility that GMO food products may cause allergic reactions, gene transfer, and outcrossing.

1) GM food products may affect allergic reactions.

Many GMO food products contain unknown or untested microorganisms as possible allergy contributors. Genes from non-food sources and new gene combinations can trigger allergic reactions in people who consume them or exacerbate existing ones. According to Nordlee et al. (1996), Brazil nuts, one of the MGO food products, were banned from circulation because they induced allergies in consumers. The allergic reaction is thought to be caused by specific gene engineering.<sup>15</sup> In principle, gene transfer from allergenic-caused food is undesirable unless proven that the protein produced by gene transfer is not allergenic. Although traditionally produced food products have not been tested for allergies, GMO food products must go through a range of testing procedures. FAO and WHO have prepared a testing and evaluation protocol for GM food products to be distributed. There has been no evidence of an allergenic reaction to GMO food products on the market.

2) Gene Transfer

The transfer of genes from GMO food products into body cells raises concerns if the transferred genes can cause harm to human health. It is possible if antibiotic-resistant gene transfer is used in the GMO food product manufacturing process, but it is pretty unlikely. In the body of transgenic organisms, it allows antibiotic resistance marker genes to be inserted into certain plants and transferred to disease-causing microbes in the intestines of humans or animals that consume GMO food products. This phenomenon had the potential to result in antibiotic-resistant microorganisms in live communities, as well as antibiotic-resistant human health issues (Bettelheim, 1999; Hileman, 1999).<sup>16</sup>

3) Outcrossing

Outcrossing is the transfer of genes from genetically modified plants to plants of other related species in nature, for example, mixing post-harvest products from conventional plant seeds with genetically modified plant products. Some countries have implemented a separation strategy between agricultural land for genetically modified crops and agricultural land for conventional crops.

With public concern about PRG, it is necessary to apply the precautionary principle and a structured system that regulates and assesses the safety and risk factors of GM food products. On the notion that alien, foreign genes might alter the nutritional value of foods in unexpected ways, reducing or increasing some nutrients and other nutrients, GM food products are assumed to be the cause of numerous diseases. Therefore, the government conducts a series of safety assessments of genetically engineered products as a responsibility to the community.

Procedures for assessing, releasing, distributing, and using GMO food products are regulated in Chapter V of Government Regulation No. 21 of 2005. The assessment is based on a written application submitted by the applicant to the authorized Minister or the head of the authorized Non-Ministerial Government Institution (LPNK). The head of the authorized Non-Ministerial Government Institution (LPNK). If applying for a permit for release to the environment, then the authorized Minister or the head of the authorized LPNK submits a request for a recommendation for the environmental safety of PRGs to the Minister. Authorized Minister is the Minister who is responsible

for the environment. In the context of providing recommendations for the biosafety of GMO food products, the authorized Minister or the Head of the authorized LPNK is assisted by the Biosafety Commission (KKH) and the Biosafety Technical Team (TTKH) to conduct a review of technical documents and further tests if necessary. The Biosafety Clearing-House (BKKH), as the Biosafety Commission (KKH) apparatus, announces the receipt of the application, process, and summary of the assessment results in an accessible place for the public to provide an opportunity for the community to submit their responses. Biosafety Commission (KKH) submits recommendations for environmental safety to the Minister, recommendations for food safety and feed safety to the authorized Minister or the Head of the authorized LPNK. The authorized Minister or the head of the authorized LPNK must base their decisions on the biosafety recommendations of the Minister or the Chair of the Biosafety Commission (KKH). The authorized Minister or the Head of LPNK issues release and distribution permits following applicable laws and regulations for GMO food products that have received biosafety recommendations and can be used for needs in various fields following their designation permits.<sup>17</sup>

## Conclusion

Legal regulations for genetically modified products in Indonesia are already very strict with the ratification of the Cartagena protocol; it is Law no. 21 of 2004 on Ratification of the Cartagena Protocol on Biosafety to The Convention on Biological Diversity and also strengthened by Law No. 8 of 2012 on Food.

The government has a role to play in ensuring the safety of genetically altered products for public health by conducting a series of studies on genetically modified food products before being distributed to the public by establishing a Biosafety Commission.

Therefore, we suggest that there is a need for biosafety regulatory analysis and decision-making on biosafety evaluation in Indonesia. Moreover, There has to be a massive public education campaign about the benefits and risks of genetically modified food products.

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