明治学院大学

Labeling Restrictions of Genetically Modified Crops in Japan: Comparison with China, the EU and the US

TAKADA Hiroshi

Abstract

Genetically modified organisms (GMOs) are one of the most important technology forms to overcome future food crises. However, it is possible that GMOs, including genetically modified (GM) foods, may affect the human body. Here, I study the legislative regulations that Japan should adopt concerning legal GMO issues, compare them with the approaches to GMOs by China, the EU and the US, and particularly emphasize the necessity for a strict labeling system of GMO foods.

1．Introduction

Recently we have been facing abnormal weather due to global warming, occurring frequently throughout the world. The desertification(1) of the Earth has been progressing at a scale of approximately 60,000 square kilometers each year, causing soil deterioration. Nonetheless, the world's population is expected to exceed 9 billion in 2050(2). Therefore, forecasts predict the necessity of increasing global the production of food by more than 1.5 times the production in 2000 in order to nourish the world's total population in 2050(3).

To overcome future food crises, the genetically modification technique(4)

attracts attention. This is technological innovation developed rapidly in the 21 st century. In particular, a genome editing technique has been developed to directly alter the targeted gene in advance, and it has also been introduced into the conventional gene-modification technique with many uncertainties and poor efficiency. We are entering the era of enabling increased production and stable supply of food, including animals, by using the genetically-modification technique.

However, there is a possibility that genetically modified organisms (hereinafter "GMOs"), including genetically modified (hereinafter "GM") foods(5), may affect the human body. Therefore, people in general are concerned about the safety and biodiversity of GMOs. In particular, the European Union (hereinafter "EU") tends toward strengthening regulation, as France has banned GMO cultivation. Conversely, in the United States (hereinafter "US"), the seed business giant "Monsanto"(6) and other huge biotechnology business enterprises are developing GMOs and deploying their businesses globally(7). And recently China produces GMOs remarkably.

Japan's food self-sufficiency rate is the lowest among developed countries, at less than 40 %, with imported many agricultural products(8). In particular, Japan imports and consume a large amount of GM maize and soybean products from the US. For this reason, Japan cannot disregard GMO safety issues.

There are many opinions and thoughts regarding the advantages and risks of GMOs, in this paper I study the legal regulations that Japan should adopt concerning the legal GMO issues(9), and compare them with those followed by China, the EU and the US, focusing particularly on whether a GMO strict labeling system of GMO foods are necessary.

2. Genetically modified crops

2.1 What is a GM crop?

The gene modification technique is used to remove DNA (deoxyribonucleic acid) from cells, change the composition and arrangement of genes, and place them in the original organism or cells of another organism. For example, we can make herbicide tolerant crops[10] that are not affected by a specific herbicide, and both pest-resistant crops and virus-resistant crops that can protect against pests without using an insecticide.

The world's largest GMO producer is the US, with a planting area of 73.1 million hectares. Typical agricultural products are maize, soybean, cotton, rapeseed, sugar beet, alfalfa, papaya, etc. The second largest GMO producer is Brazil, with 42.2 million hectares, growing soybeans, maize and cotton. The third largest is Argentina, with 24.3 million hectares. GMO's acreage area is characterized by many states in Central and South America, as well as the US (as of 2014)[11].

Regarding GMO products, soybeans are the most popular, and about 82% of the world's total soybean planting area of 111 million hectares is GM crops. Next is maize, about 30% of the total acreage of area 184 million hectares are GM crops. The next is cotton, with about 68% of the total cultivated area of 37 million hectares being GM crops (as of 2014)[12].

Japan's maize import volume is 15.0 million tons, accounting for 98.3% of the total, of which 12.6 million tons are imported from the US, representing 82% of Japan's total maize imports. For soybeans, Japan imports 2.8 million tons, which

is 91.6% of the total, with 1.8 million tons imported from the US; thus, soybeans produced in the US account for about 60 % of Japan's total soybeans import volume (as of 2014)[13].

2. 2 Advantages of gene recombination technology

The principal of benefits of using gene modification technique are the creation of innovative new varieties and the efficiency of production processes. More specifically, the advantage are the (i) production of agriculture, forestry and fishery products and foods according to consumers' tastes and desires; (ii) remarkable improvement of productivity; and (iii) contribution to solving environmental and resource problems[14].

For example, the said (i) is the production of foods excluding allergic causative substances, agricultural crops rich in nutrients and functional ingredients (such as anticancer effects), good agricultural crops, and so on. The said (ii) is the development of agricultural crops such as super high yield crops resistant to poor environment, low temperature, drying and salt damage, pest damage. The said (iii) are biodegradable plastics, environmental cleansing microorganisms, reduction of pesticide usage by imparting resistance to pest insects, development of biological energy, etc.[15].

The functions of GMOs that are commercialized are mainly (i) resistance to herbicides, (ii) resistance to pests, and (iii) daily improvement. In addition, we aim for the development of male sterility and sterility-restoration incorporation, crops containing many useful components for human body such as iron, crops to produce efficient energy production, and crops that can grow even in severe environments[16]. These developments are especially important as it is forecasted that food shortage and destruction of the global environment will become more

serious, and genetic recombination technology is expected to be one of the most important technologies for solving future food problems, global environmental problems, etc.[17].

3. Safety concerns

In 1989, symptoms such as muscle pain, dyspnea, coughing, and rash were reported in people who consumed tryptophan[18] produced using GMOs in the US[19]. Though the subsequent investigation, it was found that two unintended harmful substances ad contaminated the product. However, it is unknown whether these harmful substances are byproducts of genetic modification[20].

In August 1998, Prof. Arpad Puztai of the UK's Rowett Institute commented on the TV program that after feeding a rat a potato made pest-resistant through genetic modification, deterioration in the functioning of kidney, spleen, thymus, failure of growth in the organisms such as those in the stomach, and a drop of the immunity were seen. As a result of this report and his comments, it was told that it may lead to "suspicion of misunderstanding to the world.", and he was suspended from his job. In response to his research report, the Report Audit Committee within the Rowett Institute concluded, "This result is based on inaccurate arguments."[21]

In May 1999, Prof. J.E. Rosei of Cornell University published a paper in the scientific magazine "Nature" reporting the result of his experiment in feeding a GMOs to butterfly larvae. Having modified the milkweed butterfly pollen of maize to incorporate a gene from the bacterium called "Bt" (*Bacillus thuringiensis*), intended to protect against a pest called the European maize borer, 44% of the butterfly larvae died within four days of consuming the pollen[22].

Conversely, companies and scientists have said, "It is not strange that it was affected by Bt crops to some extent because the European maize borer and the milkweed butterfly are insects of the same Lepidoptera, ... Because insects decide plants they feed on. It is natural that even if there are things that die from the birds that do not feed on maize."[23]

In 2005, Russian researchers announced that rats born of parents who ate GM soybeans had high mortality rates and slow growth. However, the UK Food Standards Agency (UKFSA) pointed out problems with the experimental method and published statements that GM soybeans cannot be said to be the cause[24].

Study on the safety of GMO is still continued. In 2016, US National Academies of Science (NAS) had announced the result of a large-scale survey on GM crops and reported that no evidence was found to show GMO is a dangerous food.

In China, the dangers of GMOs that concern scholars are as follows[25]:

(i) Toxicity problems

Alongside the artificial recombination of genes achieving the expected effect, there is the possibility of increasing the trace amount of toxins of food.

(ii) Allergy problem

People with allergic reactions to specific foods may become prone to react foods that have not posed problems to them before. For example, adding corn genes to walnut, wheat, etc. will cause allergic reactions to these foods.

(iii) Nutritional problems

Foreign genes are likely to destroy nutritional components of food in a way unknown to humankind.

(vi) Resistance to antibiotics

Antibiotic genes are being used for the development of GM foods, and there is concern that the foods thus developed may cause the human body to have antimicrobial properties.

(v) Environmental impact

Bacterial genes are contained in many gene improvement items. These genes can produce proteins that are toxic to insects and outsources.

Confirmation of safety for GM foods concerns mainly: (i) whether the new protein of the introduced gene is safe to the human body; (ii) whether there is any allergy-causing effect on the newly produced protein; and (iii) whether the enzyme produced by the antibiotic resistance gene, often introduced together with the target gene, affects the human body. In each of these cases, however, deterministic results have not yet been obtained for GMOs in the current situation.

In these circumstances, the proponents contend, "GM foods are as safe as conventional foods", while the opponents argue, "Despite the possibility of producing unforeseen circumstances, safety. It is nonsense that it is being evaluated."[26] [27]

4. Labeling restrictions in Japan

In Japan, since April 2001, cultivation and distribution of GMOs that have been confirmed as posing no threat on biodiversity and safety as food and feed are approved[28]. However, as there is strong resistance from consumers, commercial cultivation is, essentially, not conducted in Japan. As noted above, Japan imports

many GMOs from overseas, especially from the US, as raw materials for livestock feed and processed foods[29].

Currently, the distribution of GM foods, including soybeans and maize, is permitted after completion of safety review based on the Food Sanitation Act and the Food Safety Basic Act. Regarding feed, the distribution of feeds confirmed to be safe is permitted based on the Act of Concerning the Secure of Feed Safety and Improvement of Quality (hereinafter referred to as the "Feed Safety Act") and the Food Safety Basic Act[30].

The labeling system of GM foods has been implemented in Japan since April 2001 based on the Food Sanitation Act[31], the Act of Concerning the Standardization of Agricultural and Forest Products and Quality Labeling[32] (JAS Act), and the Health Promotion Act[33]. However, in June 2013, these were unified and promulgated as the Food Labeling Act[34]. As at April 10, 2014, the GM foods and additives that are announced to have undergone the procedure of safety review are 9 potato, 28 soybean, 3 beet, 206 maize, 21 rapeseed, 45 cotton, 5 alfalfa, and 1 papaya products. In total, there are 290 products, of 8 crop species[35]. As described above, "GMO" should be indicated in the GMO itself and its processed products. However, there are some exceptions.

For example, if there is no recombinant DNA or protein produced by it, it is not obligatory to label; that is, if the introduced gene or generated protein is decomposed in the course of processing, such as heating or purification, and cannot be detected by the current analytical technique, it is assumed that there is no labeling obligation. The reason for this is that, given the impossibility of detecting evidence of a substances even after the inspection, it cannot be confirmed whether the raw material is a GMO. Therefore, even if the raw material is a GMO, if it cannot be confirmed that it is a GMO, there is no

obligation to label[36].

However, since maize oil and soybean oil are made from maize and soybeans imported in large quantities from the US, it is easy conceivable that most of these oils are made from GMOs. Rapeseed oil and soy sauce are not included in the labeling, but we cannot deny the possibility that many of these products are made from GMO[37]. Therefore, the foods currently subject to labeling as "genetic recombination" are limited to tofu (bean curd), natto (fermented soybeans), miso, soymilk, cornstarch, etc.

If the GMO is not the "main raw material", there is no obligation to indicate "genetic modification". "Main raw materials" are those in the top three in terms of percentage content of all raw materials in processed foods and the weight proportion of which exceeds 5 %. Raw materials are to be stated in descending order of weight, but there is no obligation to label GMOs not within the top three: for example, even if a GMO ranks 4th in terms of percentage content, there is no obligation to label.

Furthermore, there is no obligation to label unintentional inclusion, provided the weight percentage is 5% or less. For example, a GMO may be mixed in with another product during transportation, but if the weight is 5% or less, there is no obligation to label.

In addition, if the packaging or container area is less than 30 square centimeters, or in the case of so-called "face-to-face sales" such as prepared food store and restaurant, there is no obligation to indicate GMO content. Thus, although there are some obligations to indicate GMO as detailed above, there are some exceptions, and it can, thus, be argued that the labeling system of GMOs is not perfect in Japan[38].

The specific indications of "genetic recombination" are as follows: (i) indication

of "genetic recombination"; (ii) indication of "genetic recombination incompatibility"; (iii) indication of "not genetic modification"; and (iv) no indication.

In the case of GMOs where sorting management has been correctly performed in the manufacturing and distribution processes of food manufacturers, wholesalers, and retailers from the farm, "genetic recombination" is indicated as "genetic modification". Conversely, "not genetically modified" can be indicated only in cases in which non-GMOs are separated from GMOs in the distribution process of raw materials, and issues and acquires certificates every time they cross the distributor and distributor, importer and distributor. The method of managing commodities in this distribution process is called identity preserved (IP) handling. The indication of "not genetic modification" is optional and not mandatory. However, even if not intentional, if the contamination rate of GM crops is greater than 5% in the distribution process, it cannot be indicated as "not genetically modified"(39).

The indication of "genetic modification incompetence" is a labeling method in the cases in where the above separation management cannot be correctly proved by the document. Where one or more GMOs is used, if separation control cannot be evidenced by the document, it does not mean "genetic modification" but indicates "genetic recombination insolvency"(40).

Although these labeling methods are intended to provide useful information for consumers, the labeling method is difficult for them to understand. Therefore, it is difficult for consumers to select and purchase foods or crops based on full understanding of the labeling system. In particular, the indication of "genetic modification incompetence" does not clearly state whether foods or crops contain GMOs. There is a possibility that GMOs may have been used even if there is no

indication. Therefore, this could cause misunderstanding and confusion for consumers[41].

5. Labeling restrictions in China, the EU and the US.

Each country has its own regulations and restrictions on GMOs, which tend to differ between countries. For example, China was the first country in the world to conduct commercial cultivation of GM crops (tobacco) in 1988. In China, GMO research is indispensable for improving food self-sufficiency in the future; however, while the research and development of GMOs are strongly promoted, they are strictly regulated. In the EU, the current GMO labeling system focuses on the production process; labeling is required whenever gene recombination technology is used, even if no DNA or protein remains in the final product (Process Regulation). Conversely, the US focuses on the final product and does not impose a labeling obligation where the final product is substantially different from the conventional product, even if genetic engineering technology is used (Final Product Regulation)[42]. Japan, China, Korea, Australia, etc. are in an intermediate position[43]; however, Japan adopts a labeling system that is rather similar to that of the US[44].

5. 1 China

5.1. 1 Recent GMO business in China

To support its population, China has aggressively introduced agricultural technological innovation, including, e.g., hybrid rice. In 2014, 3.9 million hectares of GM crops were grown at in China, which is actively introducing genetic recombination technology. Since 1997, six kinds of GM plants (cotton, tomato, peppers, petunia, poplar, and papaya) have been commercialized in China.

However, most of the cultivated area of GM crops is devoted to pest-resistant cotton. Regarding rice (hybrid indica variety) and maize, a safety certificate was issued in 2009 , but it has not proceeded to the subsequent variety registration phase (the safety certificate expired in five years and was updated thereafter). Regarding soybean, although development by genetic recombination is in progress, approval has been delayed by consideration of consumer acceptance. Nonetheless, the government actively promotes the research and development of crops, animals, and forest trees by genetic engineering technology, and research and development investment in this field is considered to be the largest public institution in the world(45).

As a topic of recent GMO business, China's chemical industry leader, China Chemical Industry Group, acquired Swiss agricultural chemicals and seed giant Syngenta (Syngenta AG) for 43 billion dollars (about 5.1 trillion yen) on February 3 , 2016 . This is the largest ever acquisition of a foreign company by a Chinese company. Syngenta boasts one of the world's largest agricultural chemicals, one of the world's largest seeds, and has state-of-the-art technology in the field of biotechnology, such as a 5 trillion yen acquisition of Syngenta. Monsanto actually made several proposals, but Syngenta refused all of them, considering the valuation to be too low. Subsequently, China Chemical Industry proposed its own acquisition, which was ultimately successful(46).

There are many concerns that Chinese companies will emerge in pesticide and seed industry. In particular, it is questionable whether China can properly manage the GMOs, applying and regulating the standards of which are extremely difficult.

5.1.2 Regulations in China

The first regulation on biosafety related to GMOs in China, the Safety Management Regulation on Genetic Engineering was introduced by the Ministry of Science and Technology of China in 1993. In this regulation, the administrative department responsible for each field to which the genetic recombination technology is applied was to set specific implementation regulations. Regarding agricultural crops, the agricultural department responsible for this was decided to establish the rules. In response, in 1996 , the Agricultural ordinance Agricultural Organization Genetic Recombination Complete Management Implementation Regulations was promulgated. Also in 1996 , the Agriculture Department established an agricultural genetic recombination safety room.

Subsequently, since 2001, the basic scheme of biosafety has undergone a major change. In May 2001 , the State Council's "Agricultural Genetic Recombination Biological Safety Ordinance"[47] (hereinafter referred to as the "Ordinance") was promulgated and the 1996 regulations were abolished. In addition, in January 2002 , the Ministry of Agriculture promulgated the Genetic Recombination Biological Safety Assessment and Management Regulation (evaluation management regulation), Agricultural Genetically Modified Biological Import Safety Regulation (import regulation), and Agricultural genetically modified organism labeling control rules" (labeling regulations)[48].

As an administrative system for safety assessment, Article 5 of the Ordinance establishes "Joint Meeting System for Safety Management Division of Genetically Modified Organisms" to discuss and cooperate on important matters concerning safety management projects. However, the agricultural department is responsible for all aspects of screening, approval, distribution, and labeling of agricultural genetically GMOs (Ordinance Article 4).

The Agriculture Department that conducts the safety assessment of living modified organisms establishes "agricultural genetic recombination biosafety committee" within the department (Ordinance Article 9) and conducts safety assessments from an expert point of view. After the laboratory-level experiment, a safety assessment is conducted in three steps: "intermediate test," "environmental release test," and "productivity test" (Ordinance Article 13). The "interim test" is a small-scale study conducted within a controlled system or environment. The "environmental release test" is a mid-sized test conducted by taking safety measures under the preconditions. The "productivity test" is a relatively large-scale test conducted before commercial production. These tests must be submitted to the Agriculture Department. After the last "productivity test", an application for a certificate of safety is submitted to the Agriculture Department, which issues a certificate if approved. If a safety certificate is issued, commercial cultivation becomes possible. The safety certificate expires after five years(49).

The health and environmental safety of GMOs is classified into four levels. Level I has "no risk", Level II has a "low level of risk", Level III has a "medium level of risk", and Level IV has a "high level of risk" (Ordinance 6). The applicable level for each GMO is determined from the results of comprehensive evaluation of the safety of each of the receptor, transgene, and gene introduction method(50). Regarding GM agricultural crops, in general, there are many levels(51). To date, many Bt cottons have been approved, but with soybeans and rice, the approach has been cautious.

In the circumstances, the Food Safety Act came into force in June 2009. This legislation was enacted for the purpose of guaranteeing food safety and ensuring the protection of public health. The Act consolidates the food safety management

system in China and improves longitudinal division management for each division so far, China's other laws related to food safety include the Agricultural Product Quality Safety Law and the Import and Export Commodity Inspection Act "; however, the Food Safety Act is the core of the country's food safety management system[52]. Regarding GMOs, this Act newly stipulated that when GM foods are produced and handled, they must be clearly already prescribed in Article 16, item 3 of the "Food labeling control provision" (final revision October 22, 2009)[53].

5.1.3 Labeling of GMO

Regarding label regulation, labeling is required for foods produced from raw materials derived from GM organisms and recombinants, and labeling obligations are also imposed on oils and feeds. However, with respect to oil, there is technically a possibility that it cannot be determined whether DNA is derived from a GMO unless DNA is detected from among them. In addition, although there are no stipulations about the unintentional inclusion level of GMO's, in principle, the obligation to indicate arises if any GMO is detected at all. Thus, in China, the obligation to indicate GMO is essentially imposed[54].

Currently, the crop species subject to GMO labeling obligations in China are soybean (including soybean seed, soybean flour, soybean oil, and soybean meal), maize (including maize seed, maize oil, and maize meal), rapeseed (rapeseed seeds, rapeseed oil, rapeseed meal), cotton (including cotton seed), and tomatoes (including tomato seeds and tomato ketchup). Ultimately, it aims to introduce a monitoring system for food manufacturers and processors. However, thresholds that allow unintentional inclusion are not explicitly stipulated[55].

There are two cases of importing GMOs into China: for the purpose of domestic production, such as seeds and livestock, and simply importing as raw

materials for materials and processing. Both require obtaining a safety certificate from the Agriculture Department. In the former case, three steps (intermediate test, environmental release test, and productivity test) of recombination safety in the country are applied and the import procedure can be commenced after the safety certificate is issued (Ordinance Article 32). In the latter case, an application for safety assessment is submitted to the Agriculture Department; if this assessment is passed, a safety certificate will be issued and the importer can enter the customs clearance (Ordinance Article 33)[56].

5. 2 The EU

As of January 2016, registered GMOs approved by the EU approved comprise is 57 products of five crops species, i.e., soybean, maize, cotton, rapeseed and sugar beet. These can all be sold and distributed within the EU[57]. Regarding recombinant microorganisms approved only for feed production, there are two varieties: GM bacteria and GM yeast[58].

Regarding indications concerning GM foods, stipulations are contained in EU Regulation 1829/2003[59] and EU Regulation 1830/2003[60], and foods containing raw materials produced from GM foods and GMOs are subject to labeling obligation[61]. If generated from GMOs, they must indicate everything, regardless of whether DNA or protein is detected in the final product using GMOs. Therefore, additives, processed foods, feeds and perfumes produced directly from GMOs, such as GM soybeans, are all subject to this labeling obligation[62].

When using GMOs or raw material produced from GMOs, it is indicated as (i) “Genetic recombination” or “Produced from genetic recombination (raw material name)”. And when the raw material is a classification name, it is indicated as (ii) “Containing genetically modified (crop name)” or “genetically modified (crop

name) (including raw material)". Further, in the case of foods whose characteristics or attributes are different from conventional foods, in addition to (i) or (ii) above, the following must also be indicated: composition, nutritional value, nutritional effect, intended use of foods, and an risk to the health of people with specific conditions[63].

However, concerning the allowance of "unintentional contamination" that is inevitable or technically inevitable, EU Regulation 1829 / 2003 provides that the labeling obligation does not apply where, in the case of a food composed of a plurality of ingredients, individual food ingredients are 0.9% or less, or in the case of foods with only one ingredient, if the ingredients are 0.9% or less. However, GMOs that may be unintentionally mixed in foods are also limited to those approved by the EU[64].

In the EU, there is no labeling system for such indications as "no genetically modified crops are included" or "genetic modification not used", but in Germany and France, these indication systems are introduced voluntarily[65].

France was one of the EU states that originally promoted GMOs actively an was the second state that was keen on outdoor testing after the US until 1997 . However, based on the opinion published by the provisional committee of the Biotechnology Senior Organization, France banned the cultivation of Monsanto's GM, pest-resistant maize, "MON 810 ". This was a GM crop that the only cultivation was allowed in the EU at that time. France promulgated "a ministerial ordinance dated February 7, 2008 concerning the suspension of planting of seeds and seedlings of genetically modified maize"[66].

More recently, in March 2014 , France adopted a ban on the sowing of "MON810" seeds, and in May 2014, it proposed a bill prohibiting the cultivation, sale and use of GM maize in the domestic market. The substantive objective of

this bill is to prohibit "MON 810". This demonstrates that, even if a GMO has been approved at the EU level, there may nonetheless be a risk to the environment[67]. In this way, the EU regulates mainly through directive, but some states within the EU have their own stronger some regulations, such as France.

As of October 2015, the European states and regions banning GMO comprise Poland, Slovenia, Serbia, Croatia, Latvia, Italy, Germany, Scotland, Wales, Lithuania, Austria, Ireland, France, Greece . Conversely, Spain has a high penetration rate of GM maize GMO and is cultivated there. In Portugal, Czech Republic, Slovakia and Romania in other states, and among EU member states, GMO regulation varies.

5. 3 The US

The US succeeded in artificially transforming Escherichia coli using genetic recombination technology in 1973 , and the full-scale commercialization of GM crops began in the US in 1996[68]. From the beginning, the US has been the world leader in GM crops, and it produces about half of the world's GMO (48%) in 2013.

Crops produced by biotechnology (effectively GMOs) should "regulate crops themselves, since they are basically the same as traditional crops (substantial equivalence). So we should not regulate the process of recombination."[69]

In addition, based on the "Statement Policy - Foods Derived from New Plant Varieties"[70] publicized in May 1992, the US are reviewing the safety of GM foods. This policy is not based on law, but was rather implemented as a guideline. Regarding labeling, in the case of any significant difference from existing foods, such as nutrient modification or a new allergen, it must be indicated. However, there is no system to compel mandatory labeling[71].

When the labeling of foods causes false identification or misidentification, this

is regulated by Federal Food, Drug, and Cosmetic Act[72] (FDCA). If no information is provided in circumstances where it should be, risks to public health and the environment may arise, causing consumers to misunderstand; alternatively, where consumers may incorrectly believe in the nutritional value and functions of foods, special indication is required[73].

However, at the Food and Drug Administration (FDA) has applied the concept of "Generally Recognized As Safe" (GRAS)[74] and mot GM foods escape stringent pre-screening as food additives. This excludes GRAS substances from the definition of food additives in the FDCA. Regarding GRAS substances, many are derived from nature and only a small number of chemical additives are considered, but these are not considered to be food additives and are, therefore, not subject to food additives regulation[75]. Therefore, in the US, even if it is GMO or food additives, it will avoid regulation through the GRAS exception.

Regarding this, in 1992, the FDA announced that "Most of the genetically modified foods are considered to be GRAS, as most new plant-derived foods are widely accepted as safe." A lawsuit was filed against the FDA's policy decision in 1992 , but the court ruled that "the estimation of GRAS for genetically modified foods by FDA is not arbitrary"[76].

Also, in the US, "Final Guidance for Industry on the Regulation of Genetically Engineered (GE) Animals"[77] was issued in 2009 . Recombinant animals are managed under the provisions of FDCA's "new animal drugs" and are subject to approval prior to release into the market regardless of the application. Regarding food labeling of transgenic animals, this is only obligatory if the animal differs from conventional ones, such as a marked difference in nutrients, but voluntary indication is allowed provided it does not induce consumer misunderstandings. Note that, at present, there are no GM animals for food use[78][79].

6．Labeling restrictions

The reason that legal restrictions for GMOs exist is that GMOs may still have a negative impact on the human body; at least at this stage, we cannot categorically assert that GMOs are safe. However, this issue is not limited to GMO: all foods existing in nature are not completely safe for human beings, nor are artificial foods perfectly safe for human health. If a certain tolerance to risk is acceptable, there is no need to regulate. Conversely, if strict regulation were to be imposed on all food ingredients, the food eaten by humans is very limited.

From this viewpoint, in the US, the GRAS concept is applied. Therefore, there is no labeling obligation except for where a GM food is seriously different to its unmodified equivalent, such as nutrient modifications or new allergens. Meanwhile, the EU does not apply the concept of GRAS, but instead adopts the regulation method focusing on process, accompanied by a strict labeling system. In particular, the number of counties banning all GMOs, like France, appears to be rising.

The difference between these regulation and labeling methods is due to differences in the degree of recognition of GMOs' influence on human health. Numerous studies arguing that GMOs are not safe foods for humans and may pose health hazards have been published: if their findings and assertions are true, continuing to use GMOs as foods is tantamount to suicidal, and a major danger of health damage would be anticipated in the future. The scale is so wide that the damage could be enormous, beyond compare with traditional pollution problems, radioactive contamination, and environmental destruction, and all citizens could suffer health damage from GMOs in the future. It can also be the

worst situation.

From this perspective, if it is possible that the government cannot guarantee protecting the health of their people, it is indispensable to indicate whether the food is a GMO pursuant to the "right to know" and "freedom of choice". For example, in the case of the drug-induced HIV problem, the Japanese government initially considering that been safe. It cannot be said that the people fully trust the government, and it is natural for them to want to be able to protect themselves.

In particular, considering the actual situation of Japan importing a large amount of GMOs, even imported goods, we should impose an obligation to indicate GMOs, in order to guarantee the people's right to know and freedom of choice. Therefore, we should have strict labeling regulations like those in the EU.

In this regard, opponents of such regulation do not unnecessarily argue that by requiring complete identification to address the dangers of GMOs, GMO sales will be restrained and the development of GMO business will be hindered. However, because GMOs are a matter directly related to the health of our citizens, while such opposition can be understood as a valid contribution to policy discussion, it is not acceptable to prioritize commercial interests over concerns of human health damage. It is a different dimension, and is not sufficiently important to deny the right to know about potential health impacts and the related freedom of choice. I believe that the economic impact of the full indication of GMOs should be left to the market principle.

If the government cannot confirm that GMOs as a completely safe food, it must make the regulation of GMO labeling more rigid and complete, thereby protecting the right to know and the freedom of choice. We should leave it to the market principle and the judgment[80].

Specifically, food labeling standards for GMO should be changed as follows;

(i) All GMO should be indicated.

- There is no labeling obligation for DNA and proteins that do not remain in Japan, whereas the labeling obligation applies in the EU whenever GMOs are used, regardless of the residual DNA or protein of the final product. So, Japan should indicate all GMOs.
- There is no labeling obligation on feed, so GM feed is subject to the obligation like the EU.
- Japan should not restrict the labeling obligation to major raw materials.

(ii) The unintentional contamination should be the same level of the EU.

The unintentional contamination is exempted from labeling provided it is less than 5% in Japan, while the EU sets the permissible GMO contamination rate, which is exempted from labeling, at a low level of less than 0.9%. So, Japan should down to the same level of the EU.

7．Conclusion and Recommendation

GMOs are one of the leading technological advances for solving the food crises that humankind may face in the near future. However, as GMOs potentially pose health risks, in the unlikely event that health hazards become a reality, it is essential to keep the damage to a minimum. In particular, for Japan, which relies on foreign imports for many foods, it is a problem that cannot be ignored; until we can say definitively that GMOs are safe, it is necessary to address the worst-case assumption.

Comparing Japan with China, the EU and the US, I think that the EU vules should be used as reference because it seems that the EU is using the strictest

rules for GMOs.

To that end, if the government cannot completely guarantee the safety of GMOs, it is necessary to give GMOs a more rigorous and complete labels to give the citizens the opportunity of choosing whether to purchase them, based on the public's right to know and freedom of choice.

In any case, Japan may need to introduce EU-style strict labeling regulation of GMOs, and leave it to the market principle and the judgment.

（1） United Nations Convention to Combat Desertification (UNCCD) defines desertification as "land degradation in arid, semi-arid, and dry sub-humid areas resulting from various factors, including climatic variations and human activities" <http://www2.unccd.int/>(as of Apr 03, 2018).

（2） United Nations Department of Economic and Social Affairs. <https://www.un.org/development/desa/en/>(as of Apr 03, 2018).

（3） Japan Ministry of Agriculture, Forestry and Fisheries (MAFF), "Points of the global Food Supply-Demand Forecast – Baseline prediction results by the world's log-terms supply and demand prediction system –", June 29 , 2014 , <http://www.maff.go.jp/j/zyukyu/jki/j_zyukyu_mitosi/pdf/2050_point1.pdf>(as of Apr 03, 2018).

（4） There are some methodologies, such as Agrobacterium, Electroporation, Particle gun, etc.

（5） It refers to agricultural crops developed using gene recombination technology and food processed with it.

（6） Monsanto is a multinational bio chemical manufacturer with its headquarters in Cleveland, Missouri, USA. German pharmaceutical and pesticide giant Bayer announced that it will acquire Monsanto. The purchase price is about $ 66 billion. The aggregate sales of both companies will reach approximately 27 billion dollars, becoming the overwhelming giant of agricultural chemicals and seeds.

（7） Hiroshi Takada, "Legal Issues on Genetically Modified Organisms: Focusing on Labelling and Traceability", *University of Toyama Economic Review (Tomidai Keizai Ronshu)*, Vol. 62 , No. 3 (2017) p. 552 .<https://toyama.repo.nii.ac.jp/?action=pages_view_main&active_action=repository_view_main_item_detail&item_id=14305&item_no=1&page_id=32&block_id=36> (as of April 23, 2017).

（8） According to the statistics of the US Department of Agriculture in 2012, Japan is the world's largest importer of maize, its amount is about 16 million tons per year, about 90 % of which are produced in the US, 88 % of which is GMO. Also, about 3 million tons of soybeans are imported annually, about 70% of which are produced in the U.S., 93 % of which are GMO. In Japan, import of genetically modified foods began in 1996.

（9） It is necessary to consider the legal problems of GMO not only from the viewpoint of food safety, but also on the ecosystem and the environment and the market economic aspect.

(10) Typical herbicide-tolerant crops include Monsanto's Roundup Ready. This is a generic name of Monsanto's GMO which made it resistant to herbicide round-up.

(11) Food Safety Committee Secretariat (FSCS), Japan Cabinet Office, "On health assessment of genetically modified foods", November 13, 2015, p.11.

(12) *Id*. at 12

(13) *Id*. at 13.

(14) Takada, *supra* note (7) at 554.

(15) School of Medicine Environmental Conservation Center, University of Yamagata (UoY), "What is GMO?" <http://www.id.yamagata-u.ac.jp/EPC/15mirai/01kumikae/kumikae.html>(as of Apr 03, 2018).

(16) *Id.*

(17) Meanwhile, it is also reported that GMO is ineffective in increasing food production, and conversely productivity declines. Food and Agriculture Organization of United Nations (FAO) states that Even without the GMO, the increasing population will be fully cultivated until 2030 <http://www.fao.org/global-perspectives-studies/en/>(as of Apr 03, 2018).

(18) One of nine essential amino acids in human beings.

(19) As a representative case, there is the Showa Denko Tryptophan incident in the US in1986 <http://www.bioethics.jp/naox_trypto-j.html>(as of Apr 03, 2018).

(20) Takada, *supra* note (7) at 555..

(21) Food Safety Department (FSD), Ministry of Health, Labor and Welfare (MHLW), "Genetically modified food Q&A", 2011, pp. 13-14 <http://www.mhlw.go.jp/topics/idenshi/dl/qa.pdf>(as of Apr 03, 2018>.

(22) John E. Losey, Linda S. Rayor& Maureen E. Carter, "Transgenic pollen harms monarch larvae", *Nature* 399 : 212 <http://www.nature.com/nature/journal/v 399 / n6733/full/399214a0.html> (as of Apr 03, 2018).

(23) MHLW, *supra* note (21), at 15.

(24) Japan Ministry of Agriculture, Forestry and Fisheries (MAFF), " 3 Main arguments over the safety of genetic modification", COMMUNICATION ON GNETICALLY MODIFIED AGRICULTURAL CROPS – THINK ABOUT FOOD AND TECHNOLOGY IN JAPAN FROM THE TREND THE WORLD, 2009, pp.22-24.

(25) Japan Ministry of Agriculture, Forestry and Fisheries (MAFF)," Introduction of genetically modified crops in China and future prospects", HEISEI 22ND FOREIGN AGRICULTURAL INFORMATION SURVEY ANALYSIS - INTERNATIONAL MUTUAL UNDESTANDING PROJECT, OVERSEAS AGRICULTURAL INFORMATION SURVEY ANASYSIS - ASIA, (2011), p. 104. <http://www.maff.go.jp/j/kokusai/kokusei/kaigai_nogyo/k_syokuryo/h22/pdf/asia_h22_00.pdf>(as of Apr 03, 2018).

(26) UoY, *supra* note (15).

(27) Takada, *supra* note (7) at 555-556.

(28) Regarding the evaluation of safety, it is described on the website of each ministry.

(29) Nobuaki Honda, "The situation surrounding genetically modified crops", *Survey and Information* No. 686, 2010, pp.5-6. <http://www.ndl.go.jp/jp/diet/publication/issue/pdf/0686.pdf>(as of Apr 03, 2018).

(30) *Id*, at 6.

(31) In order to prevent the occurrence of sanitary hazards caused by eating and drinking, regulations on safety such as additives and allergy are stipulated.

(32) In order to improve the quality of agricultural and forestry goods, regulations on quality such as raw materials and contents content are stipulated.

(33) In order to improve nutrition and public health, regulate nutrient components that affect health such as energy and carbohydrates.

(34) In order to ensure the safety when ingesting food and the opportunity for voluntary and rational selection of food by consumers, the provisions concerning food labeling of the Food Sanitation Law, JAS Law, and Health Promotion Act are integrated and food A comprehensive and unified system on the labeling. (Consumer Agency, "Outline of Food Labeling Law", June 2013) <http://www.caa.go.jp/foods/pdf/130621_gaiyo.pdf>(as of Apr 03, 2018)。

(35) Food Safety Department (FSD), MHLW, "List of genetically modified foods and additives published that the procedure of safety review was undertaken.", Feb 23, 2018. <http://www.mhlw.go.jp/file/06-Seisakujouhou-11130500-Shokuhinanzenbu/shinsazumigm.pdf >(as of Apr 03, 2018).

(36) As genetically modified foods without labeling obligation, livestock such as cattle, pig, chicken and the like who grew up eating GMO, oils such as salad oil, soybean oil, maize oil, vegetable oil, margarine, shortening, mayonnaise, soy sauce, maize Syrup, fructose, glucose and other saccharides, maize flakes, brewed vinegar, alcohol for brewing and etc.

(37) Honda, *supra* note (29) at 9.

(38) Honda, *supra* note (29) at 9-10.

(39) Honda, *supra* note (29) at 10.

(40) Regarding indications concerning genetically modified foods, see "Common Q & A on food labeling (The third collection: Regarding indication concerning genetically modified food)" of Consumer Agency Food Labeling Division, December 2003 , Revised in March 2010 <http://www.caa.go.jp/foods/pdf/syokuhin 244 .pdf>(as of Apr 03, 2018).

(41) Takada, *supra* note (7) at 559-561.

(42) Kazuyo Hirakata, "Regarding labeling system and implementation status of genetically modified foods etc in EU (Agriculture, Forestry and Fisheries Policy Research: Policy trends in foreign countries over genetically modified trees / genetically modified crops) Chapter 2 Section 6 , 2009 , p. 57 . <http://www.maff.go.jp/primaff/koho/seika/project/pdf/gm6.pdf)(as of Feb 13, 2017> (as of Apr 03, 2018).

(43) *Id.* at 57 ; European Commission (2006) "REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT on the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (COM(2006)626final)"

(44) Takada, *supra* note (7) at 561.

(45) Council for Biotechnology Information Japan <https://cbijapan.com/about_legislation/legislation_w/china/ > (as of Apr 03, 2018).

(46) Reuters <http://www.nikkei.com/article/DGXLASDX13H0J_T10C17A2FFE000/>(Apr 03, 2018).

(47) http://www.maff.go.jp/primaff/koho/seika/project/pdf/gmo3-12.pdf (as of Apr 03, 2018).

(48) Masashi Tachikawa, "Trends in regulation, liquidation and distribution over genetically modified crops in China", GMO Project Research Material No. 3 -Ministry of Agriculture, Forestry and Fisheries (2003), pp.1-2.<http://www.maff.go.jp/primaff/koho/seika/project/pdf/gmo3-1.pdf> (as of Apr 03, 2018).

(49) *Id*. at 3.

(50) *Id*.

(51) *Id*. at 4.

(52) https://www.jetro.go.jp/ext_images/_Reports/ 02 / 7 eafc 4 a 8 e 48 d 3 e 26 /ch_ foodlaw_201509.pdf; Japan Ministry of Agriculture, Forestry and Fisheries (MAFF), "About revision of food safety law in China (Q & A)", (2015) <http://www.maff. go.jp/j/shokusan/export/pdf/syokuan_hou.pdf>(as of Apr 03, 2018).

(53) JETRO, "About revision of food safety law in China (Q & A)" (2015), p.7. <https:// www.jetro.go.jp/ext_images/_Reports/ 02 /e 158 fde 3728 ea 430 /ch_foodlaw_gaiyo. pdf>(as of Apr 03, 2018).

(54) Tachikawa, *supra* note (48) at 5.

(55) Council for Biotechnology Information Japan <http://www.cbijapan.com/ wldgenetic/legislation/china> (as of Apr 03, 2018).

(56) Tachikawa, *supra* note (48) at 5-6.

(57) http://ec.europa.eu/food/dyna/gm_register/index_en.cfm(as of Feb 13, 2017).

(58) Brussels Office, "Genetically modified food regulation survey EU", 2016 , p. 4 . <https://www.jetro.go.jp/ext_images/_Reports/02/2016/35fb3fc599809788/GMO_ EUrp201603.pdf>(as of Apr 03, 2018)。

(59) REGULATION (EC) No 1829 / 2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 September 2003 on genetically modified food and feed<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003R18 29&from=EN>(as of Apr 03, 2018).

(60) REGULATION (EC) No 1830 / 2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 September 2003 concerning the traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001 / 18 / EC<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:268:0024:0 028:EN:PDF>(as of Apr 03, 2018).

(61) It is imposed for 5 years of storage of distribution records and labeling obligation.

(62) JETRO, *supra* note (53) at 6.

(63) EU Regulation 1829/2003, and EU Regulation 1830/2003.

(64) EU Regulation 1829/2003.

(65) Takada, *supra* note (7) at 563-564.

(66) Japan Ministry of Agriculture, Forestry and Fisheries (MAFF), "Regulation of GMO in EU, survey on coexistence policy with general crops" [Overseas document

survey 55], November 2009 , p.12 . <https://www.s.affrc.go.jp/docs/kankoubutu/foreign/pdf/foreign_55_1.pdf>(as of Apr 03, 2018).

(67) Reuters <http://www.reuters.com/article/france-gmo-idUSL 6 N 0 NR 2 MZ 20140505>(as of Apr 03, 2018). Regardless of the decision of the EU, Member States are authorized to ban cultivation independently.

(68) Regarding the history of development of GMO, see Yutaka Tabei, "Chapter 1 Hisory of GMO", Kosaku Murata and Makoto Shimizu, BOOKS THAT UNDERSTAND GENETICALLY MODIFIED FOODS, Hoken, 2000 , and Kesuke Kitamura, "Chapter 1 The effect of genetically modified food on breed improvement of crops", Association of Japanese Agricultural Scientific Societies , RESEARCH ON GENETICALLY MODIFIED CROPS (Series of agriculture in the 21 st century), Yokendo 2006.,

(69) Eiji Suzuki, "Regarding production situation and regulatory situation etc. of genetically modified crops in the United States", Agriculture, Forestry and Fisheries Policy Research Institute Heisei 26 Country Report: United States WTO Russia (2015 . 3) Chapter 3 , 2015 , p. 75 . <http://www.maff.go.jp/primaff/koho/seika/project/pdf/cr26_5_3_gmo.pdf>(as of Apr 03, 2018).

(70) Statement Policy – Foods Derived from New Plant Varieties <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096095.htm>(as of Apr 03, 2018).

(71) FSCS, *supra* note (11) at 19.

(72) Federal Food, Drug, and Cosmetic Act <http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdcact/>(as of Feb 13, 2017).

(73) Suzuki, *supra* note (69) at 91.

(74) "GRAS" is a safety standard certification certificate given to food additives by the US Food and Drug Administration (FDA).

(75) Suzuki, *supra* note (69) at 88.

(76) *Id.*

(77) Final Guidance for Industry on the Regulation of Genetically Engineered (GE) Animals <http://www.fda.gov/animalveterinary/developmentapprovalprocess/geneticengineering/geneticallyengineeredanimals/>(as of Apr 03, 2018).

(78) MHLW, *supra* note (21) at 19.

(79) Takada, *supra* note (7) at 568-569.

(80) Takada, *supra* note (7) at 570-572.