

CURRENT STATUS OF GENETICALLY MODIFIED FOOD CONTROL IN INDONESIA

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Introduction

Indonesian population is approximately 250 million in 2015 and increases to about 4 million a year. The increase of population requires the certainty of food supply. On the other hand, Indonesia is facing shrinkage of agricultural land due to land conversion, limited water availability, limited fossil energy, and leveling off of crop productivity. Hence, application of biotechnology in Genetically Modified Organism (GMO) production could boost food production. Nevertheless, GMO safety and risks for human consumption, animal feed and biodiversity still raise public debate. Therefore, Indonesia regulates market authorization and labelling control of GMO to assure the GMO safety and to facilitate consumer freedom of choice to purchase GMO-derived products or not.

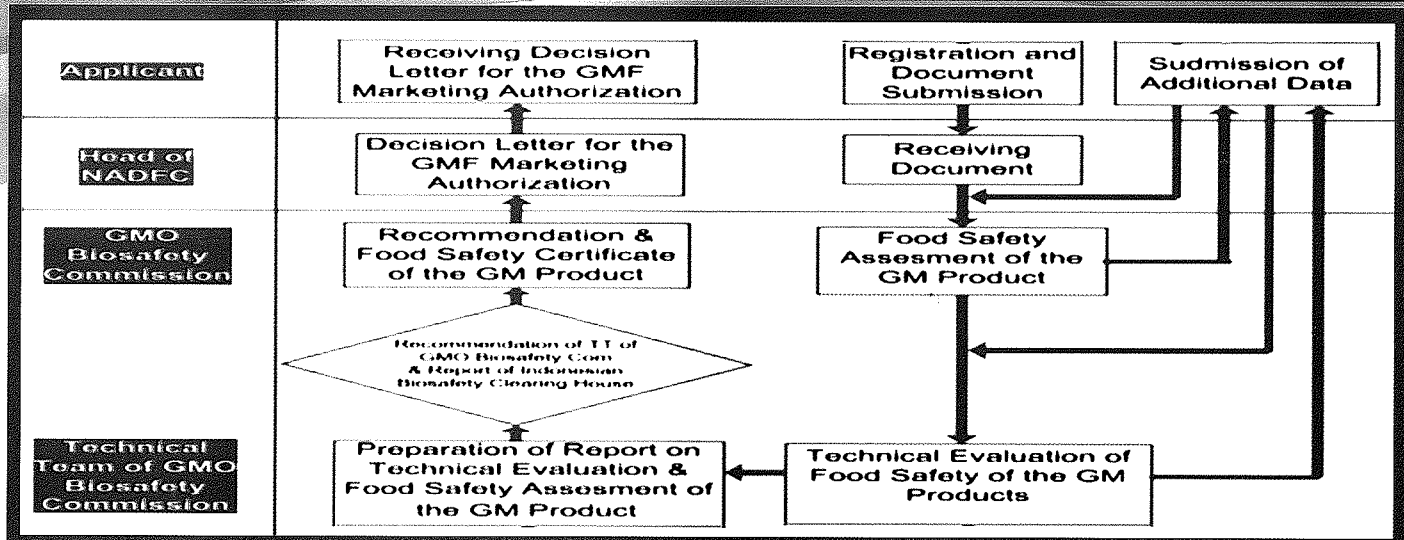


Regulatory Framework

Indonesia has established several laws and regulations related to biosafety and food safety of GMO products in the form of laws, government regulations, minister regulations, and others. The following essential laws and regulations, among others, are briefly discussed:

- **Food Law No. 7/1996**
The Food Law No. 7/1996 was the first regulation associated with the utilization of GMO products in Indonesia. It was regulated that any person who produces food or uses raw materials, food additives, and other materials in the activities or processes of food production resulting from GMO must initially examine the items in terms of food safety for human health prior to release.
- **Agricultural Minister Regulation, No. 856/1997**
This regulation covered the types, requirements, assessment procedures, rights and obligations, monitoring, controlling, and reporting of biosafety provisions.
- **Joint Minister Decree, No. 998/1999**
Since the aspect of food safety was not regulated under the Agricultural Minister Regulation No. 856/1997; the Joint Minister Decree of the Ministers of Agriculture, Forestry, and Health, as well as the State Minister of Food and Horticulture No. 998/1999 was issued on biosafety and food safety of agricultural products generated from GMO. The scope of this Joint Minister Regulation includes the setting types and uses of biosafety and food safety, procedures of biosafety and food safety, rights and obligations, monitoring, controlling, and reporting of GMO products. It covers plants, animals, fish, and microorganisms.
- **Government Regulation No. 28/2004**
The Government Regulation No. 28/2004 on food safety, quality, and nutrition was issued in regard to the utilization of GM food. It is regulated that "every person who produces food or using the raw materials, food additives, and other supplement materials in food production processes resulting from GMO must initially examine the items in terms of food safety for human health prior to release".
- **Law No. 21/2004**
The Cartagena Protocol on Biosafety to the Convention on Biological Diversity was ratified by the Law No. 21/2004.
- **Government Regulation No. 21/2005**
In this regulation, the biosafety of GMO products was associated with environmental safety, food safety, and/or food security through conditions and efforts to prevent the potential risks adversely affected by biodiversity, human, animal, and fish health caused by the processes of production, preparation, storage, distribution, and utilization of GMO products. The scope of this regulation includes the types and requirements, research and development, importation, assessment, release, distribution, utilization, monitoring, controlling, institutional, and financing the GMO products.
- **Presidential Regulation No. 39/2010**
The Presidential Regulation No. 39/2010 was issued on the setting up of the Biosafety Commission of GMO.
- **Food Law No. 18/2012**
According to this Law, food safety implementation is performed through controlling the GMO food products. There are two essential aspects related to controlling GMF. First, everyone is prohibited to produce GMO products which have not obtained food safety approval. Second, everyone who carries out food production activities are prohibited to use raw materials, food additives, and/or other materials generated from GMO processes that has not attained food safety approval.
- **National Agency of Drug and Food Control Regulation No.1563/2012**
Guideline of food safety assessment of GMO products was set by the this regulation, aiming to ensure the risk assessment carried out carefully in terms of types and requirements, mechanisms, and decisions related to food safety of GMO products.
- **Government Regulation No. 25/2012**
Guideline of environmental risk assessment of GMO products was set by the Ministry of Environmental No. 25/2012.
- **National Agency of Drug and Food Control Regulation No.1564/2012**
- **Other regulations**
Other regulations were the Agricultural Minister Regulations No. 37/2011 and No. 61/2011. The former issued on the conservation and utilization of plant genetic resources, while the latter governed the examination, assessments, releases, and withdrawal of varieties.
- **Ministry of Agriculture is drafting on feed safety risk assessment guideline**

Figure 1. Workflow of Food Safety Assesment of GM products



Biosafety Commission of GMO

Biosafety Commission of GMO consisted of government and non-government representatives was established through Presidential Regulation No. 39/2010, as follows:

- to provide recommendations of biosafety of GMO products to the related ministries;
 1. Ministry of Agriculture (food crops, estate crops and livestock & dairy products)
 2. Ministry of Forestry (forestry crops)
 3. Ministry of Marine Affairs & Fisheries (fish and aquatic organism)
 4. Ministry of Environment (Environment and biodiversity)
 5. National Agency for Drug and Food Control (processed food)
- to support the monitoring of importation and utilization of GMO products including examination and verification towards the accuracy reports related to its the negative impacts; and
- to issue certificates of food safety, feed safety and environmental safety to the related ministries as references for market authorizations.

The Biosafety Commission is supported by the **Biosafety Technical Team** to conduct technical document evaluation and detail biosafety analysis and testing. The guidelines of biosafety assesment of GMO products were prepared by the Biosafety Technical Team and approved by the Biosafety Commission. There are three Biosafety Technical Teams comprising of senior experts from various institutions (universities, researches, etc.), namely:

1. **Technical Team of Food Safety** led by National Agency for Drug and Food Control (NADFC); Workflow of Food Safety Assesment by Technical Team of Food Safety is shown in Figure 1.
2. **Technical Team of Feed Safety** led by Ministry of Agriculture; and
3. **Technical Team of Environmental Safety** led by Ministry of Environment and Forestry.

Labelling Control & Post Market Monitoring

Labelling regulation of GM Food according to the NADFC regulation No.1564/2012 are:

1. GM Food should be labelled as Genetically Modified Food in Indonesian language: ("PANGAN PRODUK REKAYASA GENETIK")
2. Specific GM logo may be added.
3. Labelled is mandatory for GM Food which have 5% threshold.
4. Exemption for highly processed food that GM protein is unidentified, e.g. oil, fat, sugar & starch.

Regulation of GM Food Registration in NADFC prior to market release are:

1. Applicant should submit testing result concerning GMO status
2. Only products with approved GMOs will be accepted.

Post Market Monitoring of approved GM Food by NADFC:

1. Regular post market monitoring of the approved GMOs is not taken in place yet, but random sampling of food is sometimes conducted to screen the presence GM products in the market.
2. Regular control of GMF labelling is not implemented yet due to limited capacity and capability of NADFC's laboratory. Testing method for GMF labelling control is being developed and validated.

Screening and Detection Methods of GMO in NADFC Laboratory:

1. Qualitative Detection by PCR and Real Time PCR
2. Quantitative Detection by Real Time PCR (still under validation process)

DNA extraction methods for raw materials:

- CTAB/QIAquick PCR Purification Kit(Qiagen#28106)
- CTAB/Wizard DNA Cleanup kit (Promega#A7280)
- CTAB non kit method
- GENESpin DNA isolation kit (cat. 5224400605)

DNA extraction methods for processed food

- CTAB+QIAamp DNA Blood Mini/Maxi Kit (Qiagen#51194)