MINISTER OF AGRICULTURE
THE REPUBLIC OF INDONESIA

REGULATION OF MINISTER OF AGRICULTURE OF THE REPUBLIC OF INDONESIA
NUMBER 36/Permentan/LB.070/8/2016
REGARDING
STUDY OF THE SAFETY OF GENETIC ENGINEERING FODDER PRODUCT

WITH THE BLESSING OF THE ALMIGHTY GOD

MINISTER OF AGRICULTURE OF THE REPUBLIC OF INDONESIA,

Considering : a. that other than having advantage genetic engineering product also has risk for the health of human being, animal, and environment;

b. that in order to minimize risk for the health of human being, animal, and environment, it is necessary to conduct study of the safety of genetic engineering fodder product;

c. that based on the consideration as referred to in letter a and letter b,

and in order to implement the provisions of Article 7, Article 13 paragraph (7), and Article 20 paragraph (4) of Government Regulation No. 21 of 2005 regarding Biosafety of Genetic Engineering Product it is necessary to stipulate Regulation of Minister of Agriculture regarding Study of the Safety of Genetic Engineering Fodder Product;

In view of : 1. Law No. 12 of 1992 regarding Plant Cultivation System (Statute Book of the Republic of Indonesia Number 46, Supplement to Statute Book of the Republic of Indonesia Number 3478);

2. Law Number 16 of 1992 regarding Animal, Fish and Plant Quarantine (Statute Book of the Republic of Indonesia Number 56 of 1992, Supplement to Statute Book of the Republic of Indonesia Number 3482);

3. Law Number 5 of 1994 regarding Legalization of United Nations Convention on Biological Diversity (Statute Book of the Republic of Indonesia Number 41 of 1994,

Supplement to Statute Book of the Republic of Indonesia Number 3556);

4. Law Number 8 of 1999 regarding Protection for Consumers (Statute Book of the Republic of Indonesia Number 42 of 1999, Supplement to Statute Book of the Republic of Indonesia Number 3821);
5. Law Number 21 of 2004 regarding Legalization of Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Statute Book of the Republic of Indonesia Number 88 of 2004, Supplement to Statute Book of the Republic of Indonesia Number 4414);
6. Law Number 18 of 2009 regarding Livestock Breeding and Animal Health (Statute Book of the Republic of Indonesia Number 84 of 2009, Supplement to Statute Book of the Republic of Indonesia Number 5015) as amended under Law Number 41 of 2014 regarding Amendment to Law Number 18 of 2009 regarding Livestock Breeding and Animal Health (Statute Book of the Republic of Indonesia Number 338

of 2014, Supplement to Statute Book of the Republic of Indonesia Number 5619);

7. Law Number 32 of 2009 regarding Environmental Protection and Management (Statute Book of the Republic of Indonesia Number 140 of 2009, Supplement to Statute Book of the Republic of Indonesia Number 5059);
8. Law Number 13 of 2010 regarding Horticulture (Statute Book of the Republic of Indonesia Number 132 of 2010, Supplement to Statute Book of the Republic of Indonesia Number 5170);
9. Law Number 39 of 2014 regarding Plantation (Statute Book of the Republic of Indonesia Number 308 of 2014, Supplement to Statute Book of the Republic of Indonesia Number 5613);
10. Government Regulation Number 21 of 2005 regarding Biosafety of Genetic Engineering Product (Statute Book of the Republic of Indonesia Number 44 of 2005, Supplement to Statute Book

of the Republic of Indonesia Number 4498);

11. Presidential Regulation Number 39 of 2010 regarding Commission of Biosafety of Genetic Engineering Product as amended under Presidential Regulation Number 53 of 2014 regarding Amendment to Presidential Regulation Number 39 of 2010 regarding Commission of Biosafety of Genetic Engineering Product (Statute Book of the Republic of Indonesia Number 127 of 2014);
12. Presidential Regulation Number 7 of 2015 regarding Organization of State Ministry (Statute Book of the Republic of Indonesia Number 8 of 2015);
13. Presidential Regulation Number 45 of 2015 regarding Ministry of Agriculture (Statute Book of the Republic of Indonesia Number 85 of 2015);
14. Regulation of Minister of Agriculture Number 43/Permentan/OT.010/8/2015 regarding Organization and Work Procedure of the Ministry of

Agriculture (State Gazette of the Republic of Indonesia Number 1243 of 2015);

D E C I D E S:

To stipulate : REGULATION OF MINISTER OF AGRICULTURE REGARDING STUDY OF THE SAFETY OF GENETIC ENGINEERING FODDER PRODUCT.

CHAPTER I
GENERAL PROVISION

Article 1

In this Ministerial Regulation, the definition of:

1. Genetic Engineering Product or Modified Organism hereinafter referred to as PRG is living organism, its parts and/or processed result which has the composition of new genetic as the result of modern biotechnology application.

2. Animal is animal which whole or part of its living cycle is on land, water, and/or air, both are raised or in its habitat.

3. Fodder is single or mixed foodstuff, either processed or not processed, to feed animal for its living, production, and reproduction.

4. PRG Fodder is Fodder containing PRG.

5. Study is the whole process of inspecting documents and testing PRG including any relevant socio-economic factors.

6. PRG Risk Assessment is the study of any possible effect damaging the environment, human health and animal health which is brought up from the development and utilization of PRG based on the application of legal scientific method and certain statistics.

7. Safety of PRG Fodder is the condition and effort required to prevent any possible harmful and hazardous impacts to animal and fish health resulting from the process of production, preparation, storage, circulation and utilization of PRG Fodder.

8. Commission of Biosafety of Genetic Engineering Product, hereinafter abbreviated as KKH PRG is the

commission with the task to give recommendation to the Minister, the authorized Minister, and Head of Non Ministerial Government Institution (LPNK) who are authorized to prepare and determine policies and to issue certificates of PRG biosafety.

9. Biosafety Technical Team of Genetic Engineering Product hereinafter abbreviated as TTKH Fodder is the team established by KKH PRG and assigned to assist KKH PRG in making evaluation and technical study of biosafety as well as feasibility utilization of PRG Fodder.

10. Head of Agricultural Research and Development Agency hereinafter referred to as Head of Agency is the leading work unit of Echelon I in the circle of Ministry of Agriculture whose duty and function is conducting the assignment in the field of Agricultural Research and Development.

11. Day is calendar day.

Article 2

This Ministerial Regulation is intended as the legal base in the implementation of Study of the Safety of PRG Fodder with the purpose of securing the Safety of PRG

Fodder.

Article 3

The scope in this Ministerial Regulation includes the types of PRG Fodder, requirements and procedures of Study of the Safety of PRG Fodder.

CHAPTER II
TYPES OF PRG FODDER

Article 4

Types of PRG Fodder include:

a. PRG plant, originated material of PRG plant, and its processed product;

b. PRG micro-organism, originated material of PRG micro-organism, and its processed product;

c. PRG fish, originated material of PRG fish, and its processed product; and

d. PRG animal, originated material of PRG animal, and its processed product.

CHAPTER III

REQUIREMENT AND PROCEDURE FOR THE STUDY OF PRG FODDER

First Section
General

Article 5

(1) PRG fodder to be distributed shall be complemented with certificate on the Safety of PRG Fodder.

(2) Certificate on the Safety of PRG Fodder as referred to in paragraph (1) shall be provided by the Minister of Agriculture upon the recommendation on the Safety of PRG Fodder.

(3) Recommendation on the Safety of PRG Fodder as referred to in paragraph (2) shall be provided by KKH PRG upon study of the Safety of PRG Fodder.

Second Section
Requirements for PRG Fodder Study

Article 6

(1) To obtain certificate of the Safety of PRG Fodder as referred to in Article 5, applicant files the application to the Minister of Agriculture through the Head of Agency pursuant to Format-1 enclosed in

the attachment which forms an integral and inseparable part of this Ministerial Regulation.

(2) The application as referred to in paragraph (1) may be filed by business entity, tertiary educational institution, government institutions, and complemented with the following requirements:

a. business entity
   1. name of company;
   2. deed of establishment and its amendments;
   3. Taxpayer Registration Number;
   4. Name of manager;
   5. Address of company; and
   6. Resident Identity Card of the company's manager or his/her attorney.

b. tertiary educational institution:
   1. name of tertiary educational institution;
   2. deed of establishment and its amendments;
   3. address of tertiary educational institution;
   4. name of head;
   5. name of researcher; and
   6. letter of assignment.

c. government institution:

1. having the task and function in accordance with the applied PRG;
2. statement from the head of work unit;
3. name of head;
4. address of the institution; and
5. name of researcher.

Article 7

(1) Besides meeting the requirements as referred to in Article 6, to conduct the Study the applicant shall complete the genetic information on PRG Fodder and information on the Safety of PRG Fodder.

(2) Genetic information on PRG Fodder as referred to in paragraph (1) covers:
a. general description of PRG Fodder;
b. description of the host and its usage as PRG Fodder;
c. description of donor organism;
d. description of genetic modification; and
e. characterization of genetic modification.

(3) Information on the Safety of PRG Fodder as referred to in paragraph (1) includes:
a. substansial equivalency;
b. change of nutrition value;
c. toxicity; and

d. other consideration.

(4) Genetic information on PRG Fodder and information on the Safety of PRG Fodder as referred to in paragraph (2) and paragraph (3) are provided in the Attachment which forms an integral and inseparable part of this Ministerial Regulation.

(5) In the event that PRG Fodder is originated from overseas, other than completed with genetic information on PRG Fodder and information on the Safety of PRG Fodder as referred to in paragraph (1), it shall be completed with:

a. certificate stating that PRG Fodder has been permitted for free trade *(certificate of free trade)* in its country of origin; and

b. documents of Study and risk management from the authorized institution where such risk assessment was once made.

Third Section
Assessment Procedure for PRG Fodder

Article 8

(1) Upon receiving the application as referred to in Article 6 paragraph (1), within the period not later than fourteen (14) Days since the receipt of the application, the Head of Agency should have

completed the examination on the completion and accuracy of documents as referred to in Article 6 paragraph (2) and Article 7.

(2) If during the examination on the documents as referred to in paragraph (1), any incompletion and/or inaccuracy is found, the application shall be returned to the applicant.

(3) The complete and accurate application shall be submitted to KKH PRG by the Head of Agency for Study of the Safety of PRG Fodder by TTKH.

Article 9

(1) Upon completing the Study of the Safety of PRG Fodder, KKH PRG shall submit recommendation on the Safety of PRG Fodder to the Minister of Agriculture in form of a recommendation:
a. safe PRG Fodder; or
b. unsafe PRG Fodder.

(2) Based on the recommendation as referred to in paragraph (1), the Head of Agency on behalf of the Minister of Agriculture shall:
a. issue the certificate of the Safety of PRG Fodder in form of Decree of Minister of Agriculture, in case PRG Fodder is declared

safe; or

b. submit the recommendation on rejection including the reason of rejection to the applicant, in case PRG Fodder is declared unsafe.

(3) The format of certificate of the Safety of PRG Fodder as referred to in paragraph (2) letter a shall conform to Format-2 provided in the Attachment which forms an integral and inseparable part of this Ministerial Regulation.

Article 10

Certificate of the Safety of PRG Fodder as referred to in Article 9 paragraph (2) shall be issued by the Head of Agency on behalf of the Minister of Agriculture not later than three (3) Days since the receipt of recommendation from KKH PRG.

CHAPTER IV
OBLIGATION OF HOLDER OF CERTIFICATE
ON THE SAFETY OF PRG FODDER

Article 11

A holder of certificate on the Safety of PRG Fodder shall be responsible for any loss either economically or

socio-culturally, resulting from PRG Fodder.

CHAPTER V
TRANSITIONAL PROVISION

Article 12

Study of the Safety of PRG Fodder which is in process, shall comply with the provisions of this Ministerial Regulation.

CHAPTER VI
CONCLUDING PROVISION

Article 13

This Ministerial Regulation commences to be effective as of the date of its enactment.

In order that all may take cognizance hereof, it is instructed to promulgate this Ministerial Regulation by its insertion in the State Gazette of the Republic of Indoneisa.

Stipulated in Jakarta
On 4 August 2016

MINISTER OF AGRICULTURE
THE REPUBLIC OF INDONESIA
signed

AMRAN SULAIMAN

Enacted in Jakarta
On 10 August 2016
DIRECTOR GENERAL OF
LAWS AND REGULATIONS
MINISTRY OF LAW AND HUMAN RIGHTS
THE REPUBLIC OF INDONESIA

signed
WIDODO EKATJAHJANA

STATE GAZETTE OF THE REPUBLIC OF INDONESIA NUMBER 1188 OF 2016

ATTACHMENT TO REGULATION OF MINISTER OF AGRICULTURE OF THE REPUBLIC OF INDONESIA
NUMBER : 36/Permentan/LB.070/8/2016
DATED : 4 AUGUST 2016

No.	Description
1.	Format-1 Application Letter for Study of the Safety of PRG Fodder
2.	Format-2 Decree of Minister of Agriculture regarding the Safety of Genetic Engineering Fodder Product
3.	Genetic Information on PRG Fodder
4.	Information on the Safety of PRG Fodder

MINISTER OF AGRICULTURE
THE REPUBLIC OF INDONESIA,

signed
AMRAN SULAIMAN

Format-1

LETTER HEAD

(date, month, year)

Ref. No. : .....
Enclosures : .....
Subject : Application for Study of Safety of PRG Fodder
Commodity .....

To:
The Minister of Agriculture
cq Head of Agriculture Research and Development Agency in Jakarta

We (Business Entity/Tertiary Educational Institution/Government Institution):

1. Name of Business Entity/Tertiary Educational Institution/Government Institution *) :
2. Deed of Establishment/Legality (enclosed) *) :
3. Taxpayer Registration Number (NPWP) enclosed :
4. Name of Head/Person in Charge :
5. Address of Business Entity/Tertiary Educational Institution/Government Institution *) :
6. Company/Institution Code Number (if any) :

would apply for a Study of Safety of PRG Fodder ..... (please mention the name/type). For your consideration, please find enclosed the documents of materials for the Study including the answers of questions to complement the said application.

Thank you for your kind consideration and approval.

Name and Signature
Head/Person in Charge,

.....

Copies furnished to:
1. Chairman of Commission of PRG Biosafety; and
2. Director General of Livestock Breeding and Animal Health

*) Delete as appropriate

Format-2

DECREE OF MINISTER OF AGRICULTURE OF THE REPUBLIC OF INDONESIA

NUMBER .....

REGARDING

SAFETY OF GENETIC ENGINEERING FODDER PRODUCT .....

WITH THE BLESSING OF THE ALMIGHTY GOD

MINISTER OF AGRICULTURE OF THE REPUBLIC OF INDONESIA,

Considering : a. that Genetic Engineering Fodder Product ..... has been examined and declared passing by the Commission of Biosafety of Genetic Engineering Product;

b. that in consideration as referred to in letter a and in order to implement the provision of Article 22 paragraph (1) letter b of Government Regulation No. 21 of 2005 regarding Biosafety of Genetic Engineering Product, it is necessary to stipulate Decree of Minister of Agriculture regarding The Safety of Genetic Engineering Fodder Product .....;

In view of : 1. The relevant Laws and Regulations;
2. ..... etc.

Bearing in mind : 1. Letter of application for Study of the Safety of PRG Fodder from ..... (applicant);
2. Recommendation on the Safety of Genetic Engineering Fodder Product ..... from the Commission of Biosafety of Genetic Engineering Product Number ..... dated .....

D E C I D E S:

To stipulate :

FIRST : Safety of Genetic Engineering Fodder Product (PRG) .....

SECOND : PRG Fodder as referred to in the FIRST dictum is declared safe for Fodder.

THIRD : PRG Fodder as referred to in the FIRST dictum shall be produced by:
1. Name of Company/ Institution *) :
2. Deed of Establishment/

Legality (enclosed) :

3. Taxpayer Registration Number (NPWP) enclosed *) :
4. Name of Head/Person in Charge :
5. Office address of the Company/Institution :

FOURTH : PRG Fodder as referred to in the FIRST dictum consists of (description of PRG Fodder):

a. .....
b. .....
c. .....
d. etc.

FIFTH : PRG Fodder as referred to in the FIRST dictum, if to be distributed and/or released, shall comply with the provisions of laws and regulations.

SIXTH : In the event that PRG Fodder as referred to in the FIRST dictum is proven to give rise to negative impact on the health of human being, animal, and/or environment, then:

a. This Ministerial Regulation shall

be revoked and declared null and void; and

b. the license holder shall withdraw the Genetic Engineering Product from circulation as referred to in the FIRST dictum.

SEVENTH : This Ministerial Decree is at the same time declared as Certificate of Safety of PRG Fodder.

EIGHTH : This Ministerial Decree commences to be effective as of the date of stipulation.

Stipulated in Jakarta
Dated

on behalf of MINISTER OF AGRICULTURE OF
THE REPUBLIC OF INDONESIA.
HEAD OF AGRICULTURE RESEARCH AND DEVELOPMENT AGENCY,

signed

.....

Copies of this Ministerial Decree shall be furnished to:

1. Minister of Environment and Forestry;
2. Minister of Maritime and Fishery;
3. Minister of Trade;
4. Minister of Industry;
5. Minister of Home Affairs;
6. Governors all over Indonesia; and
7. Regents/Mayors all over Indonesia

GENETIC INFORMATION ON PRG FODDER

1. General Description of PRG Fodder

The description covers harvest, PRG transformation process, type, and objective of modification in order to help explain the characteristic of Fodder submitted for examination of its safety.

2. Description of Host and its Usage as PRG Fodder

The required data and information of host should at least covers the following matters:

a. general name or common name, scientific name and classification of taxonomy;
b. history of cultivation, distribution and development through breeding especially to identify matters that may bring about impact damaging the health of human being, animal and/or cattle;
c. genotype and phenotype information relevant to the safety of fodder, including any known toxicity; and
d. history of usage that is safe for consumption as fodder.

3. Description of Donor Organism

Organism of donor or any other closest member in a family naturally indicates the characteristic producing toxin or pathogen or having any other characteristic influencing cattle’s health (for example when producing anti nutrient substance or toxic) needs to be determined. Description of donor organism should at least covers:

a. general name or common name, scientific name and taxonomic classification;
b. information on the history in nature that may cause problem on the safety of fodder;
c. information on any possible existence of toxin and anti-nutrient substance;
d. if donor originates from micro-organisms, information on pathogenicity and relationship to any known pathogens; and
e. information on usage history in the chain of fodder production and the way of exposure other than the usage as fodder (for example any possible existence as contaminant) shall be submitted.

4. Description of Genetic Modification

The required description of genetic modification is complete information on the process of transformation and DNA information being inserted.

a. Description of transformation process covers:
   1) Information on the specific method used for transformation (for example transformation using mediator/intermediary by *Agrobacterium* or others);
   2) Information on DNA (*interest gen)* used to modify the host (plant, microbial, viral, synthetic compound), identity and function expected in the host; and
   3) Interim host, including other organism (e.g. bacteria) used to produce or engineer DNA prior to transformation to host.

b. Information on DNA donor covers:
   1) Characteristics of all genetic component including gen marker, regulator and other elements that are influencing DNA;
   2) The size and identity;
   3) Location and orientation of sequence of DNA donor in the final vector/construction; and
   4) Function of inserted DNA donor.

5. Characterization of Genetic Modification

Comprehensive molecular and biochemical characterization of genetic modification.

Information on DNA being inserted into basic material genome includes the characteristic and description of inserted genetic substance, covering:

a. Number of inserted area:
    1) Composition of genetic substance inserted into each inserted area including data of copy number and sequence of material inserted from the surrounding area.
    2) The submitted information shall be sufficient to identify expressive genetic substance resulting from the inserted DNA fragment or if possible, any other information such as transcript analysis or expression product to identify new substance that may exist in the fodder; and
    3) Identification of the sequence of inserted DNA base, or made by inserting DNA from the organism which is genetically closed, including those produced in protein fusion.

b. Information on the materials expressed in PRG covers:
    1) Gene product (protein or non-translated

RNA) or any other information such as transcript analysis or expression product in order to determine the existence of new compound in PRG;

2) Function of gen product;
3) Description of phenotype of new characteristic;
4) Standard and area of expression in PRG gen product which is expressed and its metabolite standard in PRG, especially in the consumable part;
5) Number of gen target produced, if the function of gen sequence expressed is proposed to change the accumulation of mRNA endogen or specific protein; and
6) Non existence of gen product or metabolite changes in relation to any hazardous gen product.

c. Additional information is required for:
1) Indicating the stability of composition of any inserted genetic material, because there will be rearrangement during the integration process in the genome;
2) Indicating modification deliberately made to the amino acid sequence of the expressed protein, producing changes in

the post-translational modification or affecting the sequences which are significant for the structure or function;

3) Indicating whether the effect of the intended modification has been achieved and that all expressed characteristics have been expressed and descended to stability up to some generations, and consistent with the law of descendants.

4) Examining DNA derivative that is individually inserted or expressed in relation to RNA if phenotype characteristic cannot be directly measured;

5) Indicating that the new characteristic that is expressed conforms to that expected in the target network, with consistent function and standard and relevant regulator sequence controlling the expression of the said gene;

6) Indicating that there is some evidence to suspect that one or more genes in the receiving PRG fodder has been affected by the transformation process; and

7) Providing confirmation of the identity and expression pattern of the new protein resulting from the fusion.

INFORMATION ON SAFETY OF PRG FODDER

1. Substantial Equivalency

The concept of substantial equivalency refers to the assumption that the Safety of PRG Fodder is equal to its conventional fodder.

a. Composition of PRG Fodder.
b. Nature of Phenotype.
c. Metabolite.
d. Processing PRG Fodder.

2. Change of Nutrition

PRG Fodder which nutrition value is intentionally improved shall be assessed for its nutrition.

3. Toxicity

Information on toxicity examination of PRG Fodder shall at least cover acute toxicity against new protein and sub-chronic toxicity against PRG Fodder.