

01 703252366**THE MINISTER OF AGRICULTURE
REPUBLIC OF INDONESIA**

**DECREE OF THE MINISTER OF AGRICULTURE
NUMBER: 856/Kpts/HK.330/9/1997**

ON

**THE PROVISIONS ON BIOSAFETY OF GENETICALLY ENGINEERED
AGRICULTURAL BIOTECHNOLOGY PRODUCTS**

THE MINSTER OF AGRICULTURE

Considering:

- a. t that biotechnology through genetic engineering has rapidly developed, could give a large benefit to produce new products, but may have the possibility of being harmful to humans, biosafety and environment;
- b. grid that the utilization of genetically engineered agricultural biotechnology products must be carried out accurately, so that in its utilization the possibility of being harmful to humans and environment could be avoided;
- c. that the provisions of the existing legislative regulations do not sufficiently regulate the provisions on biosafety of genetically engineered agricultural biotechnology products;
- d. that on the basis of the above mentioned matters, it is considered necessary to regulate the use of genetically engineered agricultural biotechnology products in a Decree of the Minister of Agriculture.

Bearing in mind:

1. id Act of the Republic of Indonesia Number 6 of 1967;
2. Act of the Republic of Indonesia Number 9 of 1985;
3. Act of the Republic of Indonesia Number 12 of 1992;
4. Act of the Republic of Indonesia Number 16 of 1992;
5. Act of the Republic of Indonesia Number 5 of 1994;
6. Act of the Republic of Indonesia Number 7 of 1996;

7. Government Regulation of the Republic of Indonesia Number 15 of 1977;
8. Government Regulation of the Republic of Indonesia Number 16 of 1977;
9. Government Regulation of the Republic of Indonesia Number 22 of 1983;
10. Government Regulation of the Republic of Indonesia Number 15 of 1990;
11. Government Regulation of the Republic of Indonesia Number 78 of 1992;
12. Government Regulation of the Republic of Indonesia Number 6 of 1995;
13. Government Regulation of the Republic of Indonesia Number 44 of 1995;
14. Decree of the President of the Republic of Indonesia Number 44 of 1974;
15. Decree of the President of the Republic of Indonesia Number 15 of 1984 in conjunction with the Decree of the President of the Republic of Indonesia Number 83 of 1993;
16. Decree of the President of the Republic of Indonesia Number 96/M of 1993;
17. Decree of the Minister of Agriculture Number 280/Kpts/Um/6/1973;
18. Decree of the Minister of Agriculture Number 476/Kpts/Um/8/1977;
19. Decree of the Minister of Agriculture Number 695/Kpts/TN.620/8/1994;
20. Decree of the Minister of Agriculture Number 411/Kpts/TP.120/6/1995;

HAS DECIDED

To Determine: THE DECREE OF THE MINISTER OF AGRICULTURE ON THE
PROVISIONS ON BIOSAFETY OF GENETICALLY ENGINEERED
AGRICULTURAL BIOTECHNOLOGY PRODUCTS.

CHAPTER I GENERAL PROVISIONS

Article 1

In this Decree referred to as:

1. Genetically engineered agricultural biotechnology products which is hereinafter abbreviated to GEABP are transgenic animals and fish, and materials originating from them, transgenic plants and their parts, and transgenic microorganisms.

2. Biosafety is the condition produced through the attempts of prevention against GEABP which could disturb, harm and/or endanger humans, other life and the environment.
3. Biotechnology, through genetic engineering, are all attempts to carry out a deliberate change to the genome of living creatures by adding, deleting and/or changing the original structure of genome by using recombinant DNA technology.
4. Genome is the total genetic complement of an organism.
5. Deoxyribose Nucleic Acid hereinafter called DNA is a molecule carries genetic information of most organisms which consists of four bases and phosphate sugar as a backbone.
6. Recombinants are organisms, cells, viruses which contain recombinant DNA which is formed of the *in vitro* development of DNA fragments.
7. Transgenic animals are all genetically engineered animals living on land, either cultivated or wild life.
8. Materials originating from transgenic animals are materials originating from genetically engineered animals which could be further processed such as meat, milk, eggs, feathers, horns, nails, skins, bones, semen and honey.
9. Fish species include all other genetically engineered aquatic species which hereinafter called transgenic fish are pisces, crustacea, mollusc, coelenterates, echinoderms, amphibians, reptiles, mammals, and algae.
10. Materials originating from transgenic fish are materials originating from genetically engineered fish which could be further processed such as oil and skin of fish.
11. Transgenic plants are genetically engineered plants and their part.
12. Transgenic microorganisms are genetically engineered microorganisms.
13. Biosafety commission hereinafter abbreviated BC is the commission which has the tasks of assisting the Minister of Agriculture in compiling and determining biosafety policy in the utilization of GEABP.
14. Biosafety technical team which hereinafter abbreviated BTT is the team with the task of assisting BC in evaluating the risks and appropriateness of GEABP utilization.

Article 2

- (1) s24 This decree is intended to regulate and supervise the utilization of GEABP.
- (2) s24 The purpose of this decree is to ensure the safety and health of humans, biosafety, and the environment in relation to the utilization of GEABP.

Article 3

The scope of this decree covers the regulation of the kinds, requirements, procedure, rights and obligations, monitoring and reporting the utilization of GEABP.

CHAPTER II

THE KINDS OF GENETICALLY ENGINEERED AGRICULTURAL BIOTECHNOLOGY PRODUCTS (GEABP)

Part One

General

Article 4

The kinds of GEABP include:

Transgenic animals and materials originating from them;
Transgenic fish and materials originating from them;
Transgenic plants and their parts; and
Transgenic microorganisms.

Second Part

Transgenic animals and materials originating from them

Article 5

- (1) Transgenic animals consist of livestock, pets, laboratory animals, genetically engineered animals such as transgenic animals for pests control, and materials originating from transgenic animals.

- (2) Transgenic livestock as referred to in paragraph (1) used as food, feed, industrial raw material.
- (3) Transgenic pets as referred to in paragraph (1) are used as hobby and sports.
- (4) Transgenic laboratory animals as referred to in paragraph (1) are used as technological tool for pest control, and science.
- (5) Transgenic animals for pest control as referred to in paragraph (1) are used to control plant pest organisms.
- (6) Materials originating from transgenic animals as referred to in paragraph (1) are used as foodstuff and fodder, industrial raw material, and material for animal drugs.

Third Part

Transgenic Fish and Materials originating from them

Article 6

- (1) Transgenic fish consists of cultivated fish, pet, genetically engineered laboratory fish, and materials originating from transgenic fish.
- (2) Cultivated fish as referred to in paragraph (1) is used as foodstuff and fodder, and industrial raw materials.
- (3) Pets as referred to in paragraph (1) are used as hobby, handicraft, decoration, etc.
- (4) Genetically engineered laboratory fish as referred to in paragraph (1) is used as pests control and science.
- (5) Materials originating from transgenic fish as referred to in paragraph (1) are used as foodstuff and fodder, and industrial raw materials.

Fourth Part

Transgenic Plants and Their Parts

Article 7

- (1) Transgenic plants and their parts include food crops, horticultural crops, industrial and plantation crops, and genetically engineered products.

- (2) Transgenic plants as referred to in paragraph (1) may be used food and fodder production, medical ingredient, biological control, bio-fertilizer, industrial raw materials, bio-remediation and ornamental plants.

Fifth Part

Transgenic Agricultural Microorganisms

Article 8

- (1) Transgenic agricultural microorganisms include viruses, bacteria, protozoa, yeast, “kapang”, and genetically engineered micro algae.
- (2) Microorganisms as referred to in paragraph (1) may be used for:
- a. food and feed production processes in agricultural industry, and/or for food and feed.
 - b. bio-fertilizer, -pesticide and -herbicide, and other production inputs.
 - c. side products and agricultural wastes processes.
 - d. vaccine, antisera, probiotic, and biological materials for animals, and bioremediation.

CHAPTER III

UTILIZATION REQUIREMENTS

First Part

General

Article 9

- (1) The utilization of GEABP originating from both domestic and foreign products must pay attention to and take into consideration the religious, ethical, socio-cultural and esthetical norms.
- (2) The utilization of GEABP as referred to in paragraph (1) covers among other things the development of science, research, breeding, production and distribution including trading.

Second Part

Requirement for the Utilization of Transgenic Animals and Materials Originating from Them.

Article 10

The utilization of transgenic animals and materials originating from them must fulfil the following requirements:

- a. the name, genus and species of the animal;
- b. when a vector is used in the genetic modification, the vector used must not a pathogen element either for human beings or other organisms;
- c. complete information on the source of the genes used and the method of destruction of the remaining vector;
- d. information on the phenotypic modification as a result of genetic engineering will not cause improper side effect (for example an unproportional physical form).
- e. the genetic modification attempts carried out will not cause a change in animal behavior.
- f. information concerning the reproduction performance of transgenic animal (fertile or infertile) need to be elucidated. In case the transgenic animal is fertile, the presence of similar animal, especially those having close genetic relationships capable of cross breeding (including parents) must be explained.
- g. information on the method of eradication in case of the unwanted deviation.
- h. the kind of fodder and the manner of feeding.

Article 11

Aside from the requirements as referred to in Article 10, for transgenic livestock used for food and fodder, industrial raw material it must also be accompanied by the following information:

- a. insert stability;
- b. nutritional quality/value;
- c. natural or modified ingredient of toxic compound, anti nutritional and allergen;
- d. method used for genetic modification;

- e. molecular characterization and stability of genetic modification carried out;
- f. expression, function and effect of genetic modification;
- g. possible ecosystem change that might take place.

Article 12

Aside from the requirements as referred to in Article 10, for transgenic pets used for hobbies and sports, the following information must also be given:

- a. insert stability;
- b. natural or modified ingredient of toxic compound, anti nutritional and allergen;
- c. method used for genetic modification;
- d. molecular characterization and stability of genetic modification carried out;
- e. expression, function and effect of genetic modification;
- f. possible ecosystem change that might take place.

Article 13

Aside from the requirements as referred to in Article 10, for transgenic laboratory animals used for experiment, pest control, and science must also be accompanied by the following information:

- a. insert stability;
- b. targeted organism;
- c. expression, function and effect of genetic modification;
- d. possible ecosystem change that might take place.

Article 14

Aside from the requirements as referred to in Article 10, for materials originating from transgenic animals used for food and fodder, industrial raw material it must also be accompanied by the following information:

- a. insert stability;
- b. nutritional quality/value;

- c. natural or modified ingredient of toxic compound, anti nutritional and allergen;
- d. method used for genetic modification;
- e. molecular characterization and stability of genetic modification carried out;
- f. expression, function and effect of genetic modification;
- g. possible ecosystem change that might take place.

Third Part

Requirements for the Utilization of Transgenic Fish and Materials Originating from It

Article 15

The utilization of transgenic fish and materials originating from it must fulfil the following requirements:

- a. when a vector is used in the genetic modification, the vector used must not a pathogen element either for human beings or other organisms;
- b. complete information on the source of the genes used and the method of destruction of the remaining vector;
- c. information on the phenotypic modification as a result of genetic engineering will not cause improper side effect (for example an unproportional physical form).
- d. the genetic modification attempts carried out will not cause a change in animal behavior.
- e. information concerning the reproduction performance of transgenic fish(fertile or infertile) need to be elucidated. In case the transgenic animal is fertile, the presence of similar animal, especially those having close genetic relationships capable of cross breeding (including parents) must be explained.
- f. information on the method of eradication in case of the unwanted deviation.
- g. the kind of fodder and the manner of feeding.

Article 16

Aside from the requirements as referred to in Article 15, for transgenic cultivated fish used for food and fodder, industrial raw material must also be accompanied by the following information:

- a. insert stability;
- b. nutritional quality/value;
- c. natural or modified ingredient of toxic compound, anti nutritional and allergen;
- d. method used for genetic modification;
- e. molecular characterization and stability of genetic modification carried out;
- f. expression, function and effect of genetic modification;
- g. possible ecosystem change that might take place.

Article 17

Aside from the requirements as referred to in Article 15, for transgenic pet fish used for hobbies, handicraft, ornament, and other uses must also be accompanied by the following information:

- a. insert stability;
- b. natural or modified ingredient of toxic compound, anti nutritional and allergen;
- c. method used for genetic modification;
- d. molecular characterization and stability of genetic modification carried out;
- e. expression, function and effect of genetic modification;
- f. possible ecosystem change that might take place.

Article 18

Aside from the requirements as referred to in Article 15, for transgenic laboratory fish used for pest control and science must also be accompanied by the following information:

- a. insert stability;
- b. targeted organisms;
- c. expression, function and effect of genetic modification;
- d. possible ecosystem change that might take place.

Article 19

Aside from the requirements as referred to in Article 15, for materials originating from transgenic fish used for food and fodder, industrial raw material must also be accompanied by the following information:

- a. insert stability;
- b. nutritional quality/value;
- c. natural or modified ingredient of toxic compound, anti nutritional and allergen;
- d. method used for genetic modification;
- e. molecular characterization and stability of genetic modification carried out;
- f. expression, function and effect of genetic modification;
- g. possible ecosystem change that might take place.

Fourth Part

Requirements for the Utilization of Transgenic Plants and Their parts

Article 20

The utilization of transgenic plants and their parts must fulfil the following requirements:

- a. genus/species/cultivar of its species;
- b. when a vector is used in the genetic modification, the vector used must not a pathogen element either for human beings or other organisms;
- c. complete information on the source of the genes used and the method of destruction of the remaining vector;
- d. reproduction systems of its parents;
- e. new genetic trait inserted into the transgenic plant;
- f. information on the presence of wild relatives of the parents species;
- g. method of eradication in case of the unwanted deviation.

Article 21

Aside from the requirements as referred to in Article 20, for transgenic plants used for food and fodder must also be accompanied by the following information:

- a. insert stability;
- b. nutritional quality;
- c. natural or modified ingredients of toxic compound, anti nutrition and allergen;
- d. possibility of cross breeding with wild relative;
- e. possibility of the development of resistance to plant pests or herbicide of non target species through outcrossing;
- f. expression, function and effect of the genetic modification.

Article 22

Aside from the requirements as referred to in Article 20, for transgenic plants used for medical ingredients must also be accompanied by the following information:

- a. insert stability;
- b. molecular characterization and stability of genetic modification carried out;
- c. certain chemical ingredient including the possible efficacy and side effects (toxicity);
- d. possibility of cross breeding with wild relative;
- e. possibility of the development of resistance to plant pests or herbicide of non target species through outcrossing;

Article 23

Aside from the requirements as referred to in Article 20, for transgenic plants used for biological control must also be accompanied by the following information:

- a. possibility of insert possessing invasive characteristics;
- b. targeted organisms;
- c. possible ecosystem changes;
- d. possibility of cross breeding with wild relative;
- e. molecular characterization and stability of genetic modification carried out;

Article 24

Aside from the requirements as referred to in Article 20, for transgenic plants used for bio-fertilizer and bio-remediation must also be accompanied by the following information:

- a. insert stability;
- b. targeted organisms;
- c. possible ecosystem changes;
- d. possibility of cross breeding with wild relative;
- e. molecular characterization and stability of genetic modification carried out;

Article 25

Aside from the requirements as referred to in Article 20, for transgenic plants used for industrial raw materials must also be accompanied by the following information:

- a. insert stability;
- b. possible ecosystem changes;
- c. possibility of cross breeding with wild relative;
- d. molecular characterization and stability of genetic modification carried out;
- e. natural or modified ingredients of toxic compound, anti nutrition, and allergen.

Article 26

Aside from the requirements as referred to in Article 20, for transgenic plants used for ornamental plants must also be accompanied by the following information:

- a. insert stability;
- b. natural or modified ingredients of toxic compound, anti nutrition, and allergen.
- c. possible ecosystem changes;
- d. possibility of cross breeding with wild relative;
- e. molecular characterization and stability of genetic modification carried out;

Fifth Part

Requirement for the Utilization of Transgenic Microorganisms

Article 27

The utilization of transgenic microorganisms must fulfil the following requirements:

- a. genus and origin of parent microorganism, microorganisms source of insert, and microorganisms source of vector;
- b. presence of wild relative of parents microorganism as well as microorganisms source of vector;
- c. method of eradication in case of the unwanted deviation.
- d. when a vector is used in the genetic modification, the vector used must not a pathogen element either for human beings or other organisms;
- e. complete information on the source of the genes used and the method of destruction of the remaining vector;
- f. information on the phenotypic modification as a result of genetic engineering will not cause improper side effect (for example an unproportional physical form).
- g. the genetic modification attempts carried out will not cause a change in animal behavior.
- h. information concerning the reproduction performance of transgenic animal (fertile or infertile) need to be elucidated. In case the transgenic animal is fertile, the presence of similar animal, especially those having close genetic relationships capable of cross breeding (including parents) must be explained.
- i. information on the method of eradication in case of the unwanted deviation.

Article 28

Aside from the requirements referred to in Article 27, for transgenic microorganisms used for food and fodder production processes must also be accompanied by the following information:

- a. insert stability;
- b. material for production process produced;

- c. kind of food, method of processing before consumption, and the quality of food after processing; and/or
- d. natural or modified ingredients of toxic compound, anti nutrition, and allergen;
- e. method used for genetic modification;
- f. molecular characterization and stability of genetic modification carried out;

Article 29

Aside from the requirements referred to in Article 27, for transgenic microorganisms used for food and fodder must also be accompanied by the following information:

- a. insert stability;
- b. material for production process produced;
- c. kind of food, method of processing before consumption, and the quality of food after processing; and/or
- d. natural or modified ingredients of toxic compound, anti nutrition, and allergen;
- e. method used for genetic modification;
- f. molecular characterization and stability of genetic modification carried out;

Article 30

Aside from the requirements referred to in Article 27, for transgenic microorganisms used for fertilizer, pesticide, and other production inputs must also be accompanied by the following information:

- a. insert stability;
- b. mechanism of microbe activities as production inputs;
- c. kind of food, method of processing before consumption, and the quality of food after processing; and/or
- d. natural or modified ingredients of toxic compound, anti nutrition, and allergen;
- e. method used for genetic modification;
- f. molecular characterization and stability of genetic modification carried out;
- g. information on targeted plants.

Article 31

Aside from the requirements referred to in Article 27, for transgenic microorganisms used for processing of side products and/or agricultural waste as well as for bioremediation inputs must also be accompanied by the following information:

- a. insert stability;
- b. type and mechanism of microbe activities and the nature of the side products including the liquid, solid and gas physical characteristics;
- c. method used for genetic modification;
- d. molecular characterization and stability of genetic modification carried out;
- e. possible ecosystem changes.

Article 32

Aside from the requirements referred to in Article 27, for transgenic microorganisms used for vaccine and concealed vaccine must also be accompanied by the following information:

- a. type of vaccine (active or inactive);
- b. kind of vaccine (polyvalent or monovalent);
- c. persistence of the active vaccine in the vaccinated of or after excreted from the organism body;
- d. possibility of active vaccine mutation resulting in vaccine teratogenic effects.

Article 33

Aside from the requirements referred to in Article 27, for transgenic microorganisms used for antisera, probiotic, and biological material for animals must also be accompanied by the following information:

- a. microorganism line used;
- b. physiological characteristics of the line;
- c. direct and indirect effect on the environment;
- d. pre-clinical and clinical problems;

- e. effects of the administration of anticera, probiotic, and biological material which is administered to livestock on human beings.

CHAPTER IV

PROCEDURE FOR THE UTILIZATION OF GEABP

First Part

Application

Article 34

- (1) Every person or legal entity who will use GEABP must file a written application by using form model A to:
 - a. The Minister of Agriculture in this case the Director General of Animal Husbandry for animals, vaccine culture, anticera, probiotic, and biological material for transgenic animals;
 - b. The Minister of Agriculture in this case the Director General of Fishery for transgenic fish and materials originating from it;
 - c. The Minister of Agriculture in this case the Director General of Food Crops and Horticulture for transgenic food crops and horticultural crops, and their parts;
 - d. The Minister of Agriculture in this case the Director General of Plantation for plantation plants and transgenic industrial crops as well as their parts;
 - e. The Minister of Agriculture in this case the Director of the Center of Quarantine for microorganisms of the transgenic biological agents;
 - f. The Minister of Agriculture in this case the Pesticide Commission for microorganisms of the transgenic biological agents;
 - g. The Minister of Agriculture in this case the Director General of the Agency for Agricultural Research and Development for GEABP not included in the letters a, b, c, d, e, and f.
- (2) The application referred to in the paragraph (1) must be accompanied by the requirements in line with the kind of GEABP as mentioned in Chapter II and Chapter III of this Decree.

Article 35

- (1) The official as referred to in Article 34 after receiving the application, requests the considerations on the technical aspects of biosafety from the BC.
- (2) After perusing the application referred to in paragraph (1), the BC requests the BTT to carry out an appropriate technical study.
- (3) Upon carrying out an appropriate technical study (risk) as referred to in paragraph (2), the BTT is obligated to submit a report on the result of the technical study to BC.
- (4) On the basis of the report on the technical study results, the BC submit its suggestions/considerations or recommendations to the official as referred to in Article 34.

Article 36

In the case of the GEABP has once been utilized in Indonesia, the BC will give a suggestion, consideration or recommendation to the official as referred to in Article 34 that the GEABP can be approved for utilization.

Article 37

The composition of membership, duties, and responsibilities of the BC and BTT shall be determined with a separate decree.

Second Part

Evaluation

Article 38

- (1) The technical study by BTT as referred to in Article 35 paragraph (2) and (3) for conducting evaluation of the application by using form model B.
- (2) When BTT still requires further study through a laboratory testing, greenhouse, and special field, the applicant is requested to send a sample of the GEABP to the BTT by complying with the requirements as referred to in the form model B.

- (3) The expenses for the laboratory, greenhouse and special field tests as referred to in paragraph (2) shall be charged to the applicant.
- (4) The results of the application evaluation as referred to in paragraph (1) by the BTT shall be manifested in a report using the form model C.
- (5) Further provisions on the procedure of evaluation shall be determined by the Director General of the Agency for Agricultural Research and Development, as Chairman of the BC.

Third Part

Determination of Recommendation

Article 39

The report on the evaluation result of the BTT as referred to in Article 38 paragraph (2) shall be used as consideration by the BC to give a recommendation to the official as referred to in Article 34 by using form model D and model E.

The recommendation of BC as referred to in paragraph (1) shall be used by the official as referred to in Article 34 as the basis for the determination that the:

- a. application is approved; or
- b. denied.

In case of denial, the official as referred to in Article 34 shall issue a letter of denial to the applicant accompanied by the reasons for the rejection.

CHAPTER V

RIGHTS AND OBLIGATIONS

Article 40

- (1) Any person or legal entity who or which has obtained approval for the utilization of GEABP is entitled to obtain a protection for the secrecy of its GEABP with regard to the trade or commercial aspects.

- (2) The protection of secrecy as referred to in paragraph (1) is in the form of the protection of secrecy of the application for the utilization of GEABP which must be carried out by the official as referred to in Article 34, BC and BTT.

Article 41

- (1) Any person or legal entity who or which has obtained approval for the utilization of GEABP, in the GEABP production and/or distribution activities must give a label, so that every person could know that the commodity concerned is a GEABP.
- (2) The label as referred to in paragraph (1) may be pasted on the packing or container, or included in the GEABP commodity concerned.

Article 42

When the GEABP causes biosafety harm, the person or legal entity who or which has obtained approval for the utilization of the GEABP is obligated to participate in the control and overcoming.

CHAPTER VI

MONITORING AND REPORTING

Article 43

Any person or legal entity who or which has obtained approval for the utilization of GEABP is obligated to submit a periodical report once every six months or any time when required or in the event of biosafety harm, to the official as referred to in the Article 34 in line with the kind of GEABP.

Article 44

- (1) To know the level of GEABP utilization a monitoring shall be carried out by the official as referred to in Article 34.
- (2) In the implementation, the official as referred to in Article 34 is assisted by:

- a. The Supervisor of Animal Drugs, Pest and Disease Observer of “BPPH”, Animal Stock Supervisor, Veterinarian assigned to the Animal Slaughterhouse/Poultry Slaughterhouse, Veterinarian, Supervisor for Fodder, for transgenic animals and materials originating from them;
 - b. Supervisor of Fish Resources for transgenic fish and materials originating from it;
 - c. Insect Pests and Diseases Observer, Seed Supervisor, Pesticide Supervisor for transgenic plants and transgenic microorganisms.
- (3) The supervising mechanisms in accordance with the Decree of the Minister of Agriculture as referred to in paragraph (2).

CHAPTER VII

TRANSITIONAL PROVISIONS

Article 45

Indonesian national individuals, Indonesian legal entity, government agencies, research institutions and higher education institutions which has utilized GEABP before the enforcement of this Decree, within six months as of the coming into force of this Decree must file an application on the basis of this Decree.

CHAPTER VIII

CONCLUDING PROVISIONS

Article 46

This Decree is without prejudice to the validity of the Decree of the Minister of Agriculture which regulate:

- a. The licensing of the import and export of animals and materials originating from animals, fish and materials originating from fish, plants, biological agents;
- b. The registration of pesticides, animal drugs;
- c. The release of plant varieties;
- d. Quarantine measures.

Article 47

This Decree comes into force on the day it is laid down.

Laid down in: J a k a r t a

On September 2, 1997

THE MINISTER OF AGRICULTURE

Signed

Dr. Ir. Sjarifudin Baharsjah

A copy of this Decree is submitted to:

1. The State Minister for the Environment
2. The State Minister for Research and Technology/Chairman of the Agency for Assessment and Application of Technology;
3. The State Minister for Food Affairs;
4. The Minister of Health;
5. The Minister of Industries and Trade;
6. The Minister of Education and Culture;
7. The Minister of Forestry;
8. The Director General of the Agency for Agricultural Research and Development;
9. Chairman of the Indonesian Institute of Sciences;
10. The Director General of the National Atomic Energy Agency.

Attachment List: Decree of the Minister of Agriculture
Number: 856/Kpts/HK.330/9/1997
Dated: September 2, 1997

**LIST OF FORMS OF THE PROVISIONS ON THE BIOSAFETY OF GENETICALLY
ENGINEERED AGRICULTURAL BIOECHOLOGY PRODUCTS**

rw1 0 No.	Model Code	Name of Form	Article
rdrh 1	A	Application for the Utilization of Genetically Engineered Agricultural Biotechnology Products	34 para. 1
d 2	B	Evaluation of the Application for the Utilization of Genetically Engineered Agricultural Biotechnology Products	38 para. 1
3	C	Report of the BTT on the Utilization of Genetically Engineered Agricultural Biotechnology Products	38 para. 4
4	D	Approval Letter on the Application for the Utilization of Genetically Engineered Agricultural Biotechnology Products	39 para. 1
t5	E	Letter of Denial of the Application for the Utilization of Genetically Engineered Agricultural Biotechnology Products	39 para. 1

MINISTER OF AGRICULTURE

Signed by

DR. IR. SJARIFUDIN BAHARSJAH

MODEL A

Application Letter for the Utilization of Genetically Engineered Agricultural Biotechnology Products

Number:

Attachment:

Subject:	Application for the Utilization of Genetically Engineered Agricultural Biotechnology Products	To (The related Director General/Director General of the Agency for Agricultural Research and Development)
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We herewith:

1. Name of Company/Agency/Individual *):
2. Deed of Establishment/Legal Legality (enclosed)*):
3. Taxpayer Identification Number (NPWP) enclosed:
4. Name of the Manager/Person Responsible:
5. Address of the Office of the Company/Agency/Individual:
6. Code Number of the Company/Agency/Individual (if any):

Submit an application to obtain approval for the Utilization of Genetically Engineered Agricultural Biotechnology Products.

As the material for your considerations enclosed are data and documents concerning the answers on the questions (Enclosure 1) to complete the application referred to.

Please be informed accordingly and we thank you for your approval.

Name and Signature
Manager/Person Responsible

.....

cc to:

Biosafety Commission

*) delete the inapplicable

ATTACHMENT I

QUESTIONS FOR THE APPLICANT/BACK UP INFORMATION

- (1) The Applicant for the utilization of genetically engineered agricultural product must answer the core questions that are mentioned in Section A and the other relevant Section of the Application.
- (2) It is the obligation of those who are involve in the compilation of an Application to give an overall consideration to the Department of Agriculture on the impact that may take place as the result of the utilization proposed, and complete information concerning the relevant matters. The impact that needs to be paid attention to, includes the influence on safety and health of the community, agricultural production, other living creatures and environmental quality. Attention must be given to the experience of research on the same genetically engineered agricultural biotechnology products in a closed place.
- (3) Answer should be supported with data and the appropriate references. If the supporting data is not available, the basis of the answer should be explained. In case of any doubt in giving the correct answer to question, the nature of doubt must be explained. If it is estimated that there is a potential danger, clear and complete information concerning the existing risks must be given, and if possible, various steps which may be used to prevent and control the risks, must be considered and suggested.

A. CORE QUESTIONS

Species to be released

- A1 What species of genetically engineered agricultural biotechnology products are to be released? In case of being relevant, clarify them concerning strain, cultivar, pollution and so on.
- A2 Would such genetically engineered agricultural biotechnology products cause illnesses or disturbance to the health of human beings, plants or animals? If yes, what effects may occur?
- A3 (i) Where did the exogenous genetic material come from? Clarify it clearly.
(ii) Did such genetic material come from organism that may cause illnesses or harm the health of human beings, plants, or animals? If yes, how would the effect possibly occur?

Special purposes of the utilization

- A4 (i) What are the objectives of the application and the ultimate utilization of the genetically engineered agricultural biotechnology products?
(ii) What are the benefits of the chosen method in comparison to other methods?

Location

- A5 Clarify how many genetically engineered agricultural biotechnology products are to be released, and when relevant, the extent of land to be used, and where the location is. When relevant draw the map.
- A6 (i) What are the reasons for choosing such location?
(ii) Clarify in details the relevant nature of the physical environment, particularly those which may cause undesired consequences.
(iii) How far is the location of the said utilization from the settlements of the population, center of agricultural activities, or the habitat of the genetically engineered agricultural biotechnology products which may have an influence or be affected?

Habitat and ecology

- A7 (i) What is the natural habitat of the parent of said genetically engineered agricultural biotechnology products, and what is the extent of its scope?
- (ii) Where were the parents of such genetically engineered agricultural biotechnology products discovered for the first time?
- (iii) How is the dispersal of the parents in Indonesia?
- (iv) Are the parents already in existence at or adjacent to the location of the planned utilization? If yes, give the data pertaining to their populations.
- (v) Are the parents of the genetically engineered agricultural biotechnology products, strange in Indonesia?
- A8 Are there other organism in Indonesia acting as predator or parasites against the genetically engineered agricultural biotechnology products which are to be released?
- A9 Would the utilization of genetically engineered agricultural biotechnology products disrupt the function of the parent which are useful to the environment?
- A10 Clarify each ecological effect, directly or indirectly, that may be anticipated as a consequence of the utilization, which is not covered by the questions in the following section (B, C, D, and so on).

The genetics of genetically engineered agricultural biotechnology products

- A11 What genetic traits have been engineered? Clarify in details about the steps that have been taken.
- A12 Would the genetically engineered agricultural biotechnology products genotypically have the opportunity of becoming unstable?
- A13 (i) How far has the genetic modification been characterized? Give the data.
- (ii) At what location has the DNA been inserted and how many copies are available?
- (iii) What marker or sequence may be used to identify the genetically engineered agricultural biotechnology products at the laboratory or in the field?

- A14 (i) What types of vectors are used to carry out the transformation? Clarify such vectors, position of the inserted DNA and the sequence control or marker within the vector.
- (ii) Can the vector be transferred to another host? If yes, give the data about the dispersal of the host of vector.
- (iii) Is the recombinant vector still be found in the genetically engineered agricultural biotechnology products? If not, how to remove such recombinant vector?
- A15 In case no vector is used:
- (i) if exogenous nucleic acid exists in the genetically engineered agricultural biotechnology products, how were they inserted?
- (ii) How many copies of the genes are inserted?
- (iii) What genetical side effects are to be anticipated?
- A16 How does the genetic modification change the phenotype of genetically engineered agricultural biotechnology products that will be released? Give the data to show the effect of modification, including the level of expression and regulation of the inserted gene.
- A17 (i) If any, which intrinsic genetic trait of the genetically engineered agricultural biotechnology products could control its persistence and dispersion in nature? How stable are these traits?
- (ii) What genetic changes, if any, have been done on the genetically engineered agricultural biotechnology products to limit or to lose its ability to reproduce or to transfer its gene to other genetically engineered agricultural biotechnology products?

Contained experimental data and other research pertaining to the stability, persistence, dispersion and movement

- A18 Based on contained experiment or other relevant experience, give the data pertaining to:
- (i) the persistence of genetically engineered agricultural biotechnology products in the planned habitat of utilization;

- (ii) parental growth rate and the genetically engineered agricultural biotechnology products in the secured environment and period of utilization.
 - (iii) The frequency of reversion or losing the genetically modified traits.
- A19
- (i) How is the spreading capability of the genetically engineered agricultural biotechnology products from the place of utilization? How is the dispersal mechanism: through the air, water or ground?
 - (ii) Can the parent create a structure to survive for a long period such as seeds or spores?
- A20
- Is there any evidence of the possibility of the released traits to be transferred to the other existing organisms in the area of utilization? If yes,
- (i) into what organism and what are the frequencies? Give a list of the species tested or evaluated on its ability to receive those characteristics, and clarify the reason for having chosen them.
 - (ii) How about its transfer mechanism?
 - (iii) What technique is used to indicate the ability of receiving the characteristics or its transfer?
 - (iv) What is the adverse effect as a consequence of the transfer of such characteristics?
- A21
- Does the modified characteristics give the selective benefit to the genetically engineered agricultural biotechnology products? If yes, under what condition? Give data concerning growth rate with or without the selection pressure.
- A22
- Do you expect that the genetically engineered agricultural biotechnology products could give a competitive benefit as compared to its unmodified parent in a mix population at the testing place? If yes, what are the benefits?

Experimental procedure, monitoring and emergency planning

- A23 (i) Clarify in detail the protocol of utilization trial, the protocol of control, and testing of the genetically engineered agricultural biotechnology products.
- (ii) How many genetically engineered agricultural biotechnology products are planned to be released?
- (iii) How many genetically engineered agricultural biotechnology products are proposed to be released?
- A24 (i) What plans have been made to multiply the genetically engineered agricultural biotechnology products in a large number and its transfer to the place of the experiment (see Model B figure 3 the requirements of sending genetically engineered agricultural biotechnology products)?
- (ii) How will the genetically engineered agricultural biotechnology products be released?
- A25 (i) What method will be applied to test the inter batch variability in case the genetically engineered agricultural biotechnology products are needed in large quantity?
- (ii) What special precaution have been or will be taken in the production process to ensure the quality/purity achievement of the genetically engineered agricultural biotechnology products?
- A26 (i) How to monitor the persistence of the genetically engineered agricultural biotechnology products? Give a clarification concerning the technique of monitoring the presence and movement of the genetically engineered agricultural biotechnology products or genetic material from the testing place, including specificity, sensitivity and reliability of the method of its detection.
- (ii) In case the utilization would influence the characteristics or quantity of other species, how is the method of monitoring?

- (iii) How to monitor the gene transfer to other species?
- A27 (i) If any, what potential hazard and harmful effect could be suspected and how could that possibility be evaluated during the utilization process?
Explain each procedure applied to test the spreading of genetically engineered agricultural biotechnology products.
Should the gene transfer resulted in the adverse consequence (see question A20), what methods could be applied to minimize the consequences?
- A28 (i) Will the genetically engineered agricultural biotechnology products remain exist in the environment after the utilization trial has been completed? If yes, (a) for how long, and (b) what will be the consequence?
- (ii) Are there steps to reduce the population or to eliminate the genetically engineered agricultural biotechnology products after they have been released? If yes, give the details.
- (iii) What monitoring could be done after the trial has been completed?
- A29 What measures could be taken to eliminate the genetically engineered agricultural biotechnology products in case the danger arise during the utilization trial?
- A30 Explain all procedures of supervision and safeguarding to be done by the executors.
- A31 Explain the method of disposing of any used materials.

Other evaluation methods

- A32 Has the BC ever evaluated an application to develop a small scale genetically engineered agricultural biotechnology products? If yes, what are the results?

- A33 (i) Has the same or similar utilization ever been carried out before, either inside or outside of Indonesia? If yes, what were the beneficial and harmful consequences? Give references or report on those previous evaluation?
- (ii) Is there any country denied the application for the utilization of the genetically engineered agricultural biotechnology products? If yes, what is the basis of such denial?
- (iv) What factors would possibly cause a serious/less serious risk in the utilization proposed in Indonesia when compared to the utilization proposed abroad?
- A34 Are the genetically engineered agricultural biotechnology products imported? If yes, give the documentation concerning the licensing or evaluation of the quarantine.
- A35 Are there reasons to suspect that in case such genetically engineered agricultural biotechnology products are released, they would cause a danger which is not mentioned in the application, (a) at the region of destination, or (b) at another region in Indonesia? If yes, explain it.

B. PLANTS

In case the plants are intended for food or fodder, answer also questions included in section J.

- B1 Has the parent plant had an extended history of cultivation and safe use? If not, explain it.
- B2 If any, what unintended pleiotropic effects, including undesirable effects on the agronomic traits, may result from transgene expression in the genetically engineered agricultural biotechnology products (e.g. reduced fertility, increased

disease prevalence, loss of production, grain shattering). Indicate the likelihood of these events.

- B3
- (i) Describe the mechanisms of pollen spread of the plants (by insect vectors or by other means).
 - (ii) Provide the data on pollen viability of the plant.
 - (iii) Indicate potential pollinators and their distribution in Indonesia.
- B4
- (i) Is there any unmodified plant belonged to the same genus known as weeds? If so, specify.
 - (ii) Is there any literature report on cross-pollination between plant species similar to the genetically engineered agricultural biotechnology products with its wild species known as weeds? If so, please list.
- B5
- (i) provide quantitative data of the successful cross-pollination between such plant and its wild species.
 - (ii) If you know any plant which is sexually compatible with the genetically engineered agricultural biotechnology products in the area of intended release, give the details and quantify the chances cross-pollination.
 - (iii) If such cross-pollination took place can the offspring survive? If not, why?
- B6
- (i) Will the released plant be allowed to set seeds? If not, is that planned for the next utilization?
 - (ii) If the plant is allowed to set the seeds, is the mature seed normally remain contained within an ear, capsule, pod etc. so that practically all of the seeds can readily be harvested, or is the seed shed soon after it matures?
 - (iii) Can the seed be dispersed by natural mechanisms? If so, describe.
 - (iv) Are the seeds capable of being dormant for a long time? If so, how long?

- B7 Can the plant be dispersed by vegetative propagation? If so, describe the possible mechanisms.
- B8 (i) What is the likelihood that the inserted characteristic could be transferred into other species, with adverse consequences?
(ii) If there is any possibility of such transfer, would it have the potential to affect the distribution and abundance of the other species? If so, specify.
(iii) If there is any possibility of such transfer, has any attempt been made to minimize the risk (e.g. by inserting male sterility or other means of reproductive isolation)? If not, why?
- B9 How might the plant's competitive advantage (fitness) be change (i) in the agricultural setting, (ii) in the natural environment? Explain.
- B10 Does the new characteristic change the capacity of the plant to add substances to or subtract substances from the soil (e.g. nitrogen, toxic compounds)? If so, describe the change.
- B11 (i) Is there any possibility that the inserted gene could cause an increase in toxicity of the plant for animal and humans? If so, provide available data.
(ii) Could any products of the plant concentrate in the natural or human food chain to levels which become toxic? If so, explain.
(iii) Is the biodegradability of the plant changed? If so, how?
- B12 What the secondary ecological effects might result from release of the genetically engineered agricultural biotechnology products (e.g. effect on endangered native species, resistance of insect populations to an insecticide, reduction or increases in numbers of prey or parasites, etc.)?

- B13 If the genetically engineered agricultural biotechnology products contain resistance to a chemical agent (other than selective agents, such as antibiotics, used in strain construction):
- (i) provide data on degradability, selectivity and toxicity of the chemical concerned;
 - (ii) what is the agronomic significance of the chemical?
 - (iii) What is the biological activity of the chemical?
 - (iv) How is the chemical applied and used?
- B14 If the genetically engineered agricultural biotechnology products contain resistance to herbicide, explain whether:
- (i) the release will result in more effective use of herbicide?
 - (ii) The release will result in better weed control in the crop?
 - (iii) The release will result in a more efficient overall farming operation?
 - (iv) The release will allow a change to a program which involves environmentally friendly chemical or practices?

C. MICROORGANISMS LIVING INSIDE OR ON THE SURFACE OF ANIMAL

Question here relate to genetically engineered agricultural biotechnology products such as microorganisms within digestive tract living within a larger host and microorganisms applied on the surface of animals.

- C1 What is the animal host species?
- C2 Has the parent organism an extended history of use in agriculture? If so, please elaborate.
- C3 Is there any evident that the genetically engineered agricultural biotechnology products capable of surviving in or on other animals, including feral animals? If so, what are those animals and what are the effects?

- C4 (i) What new capacity will the genetically engineered agricultural biotechnology products provide for the host species? (e.g. ability to degrade plant or pasture toxin)?
- (ii) What secondary effects can be postulated from conferring that capacity on the host?
- C5 Will the competitive advantage or ecological fitness of the host be altered? Explain, providing data to support your answer.
- C6 What effect effects (including secondary effects) are likely on other plants or animals in the agricultural and natural environments? (Please include in your answer any possible effect on non-host animals or feral populations).
- C7 What secondary effects could be postulated from the introduction of the genetically engineered agricultural biotechnology products into or onto the host? (For example, is there a possibility of the genetic insert being transferred to other organisms in the host, or to host cells?)
- C8 For genetically engineered agricultural biotechnology products living in animals, will the genetically engineered agricultural biotechnology products be excreted or otherwise leave the animal? If so, for how long does it survive outside the animal?
- C9 (i) What is the survival and dispersal of the genetically engineered agricultural biotechnology products in natural waters and soil?
- (ii) What could be the effects of the genetically engineered agricultural biotechnology products on water quality?
- (iii) Do the genetically engineered agricultural biotechnology products produce spores?
- (iv) Are the genetically engineered agricultural biotechnology products resistant to desiccation?

- C10 (i) What sterilizing and anti-microbial agents are active against the genetically engineered agricultural biotechnology products?
- (ii) Are the genetically engineered agricultural biotechnology products susceptible to UV and ionizing radiation?

D MICROORGANISMS NOT FALLING INTO SECTIONS C

Questions here relate to microorganisms associated with plants and microorganisms which might be applied to modify the physical or chemical environment (e.g. microorganisms to modify soil properties).

- D1 For microorganisms associated with plants, what is the partner species of plant? Describe the specificity of the interaction and indicate the range of plant species with which the genetically engineered agricultural biotechnology products can interact.
- D2 Has the parent organism an extended history of use in agriculture? If so, please elaborate.
- D3 For microorganisms associated with plants:
- (i) What is the effect of the genetically engineered agricultural biotechnology products on the partner plant species and how will this be monitored?
 - (ii) What other secondary effects might the genetically engineered agricultural biotechnology products have on the plant?
 - (iii) Does the modification cause any change to the range of host plant species available to the organism?
 - (iv) What effect of the genetically engineered agricultural biotechnology products, if any, is anticipated on the distribution and abundance of the host plant species and other species with which the organism can interact?

- D4 If the genetically engineered agricultural biotechnology products is associated with plant species which are food crops, could it affect the suitability of the resultant produce for human or animal consumption? If so, explain.
- D5 What are the effects expected on soil chemistry (e.g. pH, mineral leaching, chelation, nutrient levels)?
- D6 (i) What is the survival and dispersal of the genetically engineered agricultural biotechnology products in natural waters and soil?
(ii) What are any possible/likely effects of the genetically engineered agricultural biotechnology products on water quality?
(iii) Does the genetically engineered agricultural biotechnology products produce spores?
(iv) Is the genetically engineered agricultural biotechnology products resistant to desiccation?
- D7 What effects might the genetically engineered agricultural biotechnology products have on soil organisms which are known to be beneficial to plants (e.g. *Rhizobium*, *Azospirillum*, *Frankia* and mycorrhizal fungi) and are likely to be in the test area?
- D8 What is known about interactions between the genetically engineered agricultural biotechnology products and closely related microorganisms in the partner plant (if applicable) or the environment of the site of introduction?
- D9 For genetically engineered agricultural biotechnology products associated with plants, what effect they might have on insects, birds and animals (including humans) which may eat the plant?
- D10 Does the genetically engineered agricultural biotechnology products exchange genetic material with known plant pathogens? If so, elaborate.

- D11 (i) What sterilizing and anti-microbial agents are active against the genetically engineered agricultural biotechnology products?
- (ii) Is the genetically engineered agricultural biotechnology products susceptible to UV and ionizing radiation?

E VERTEBRATES, NOT INCLUDING FISH

If these are to be consumed as a food, answer also the questions in Section J.

Questions here relate to all animals except fish. Please note that all work involving animals should be conducted according to widely accepted principles for the safe and humane treatment of experimental animals, and may therefore require review by institutional animal experimentation ethics committees, and by authorities administering animal welfare legislation.

- E1 (i) What unintended effects (to the environment, animal welfare) may result from the planned introduction, and what is their likelihood?
- (ii) Are any of the intended gains directly linked to changes in other characteristics of the species? If so, specify.
- E2 What effects might the expression of the modified trait have on the physiology, behavior and reproduction of the animal? Explain, with data (e.g. studies from model animals).
- E3 (i) Will the animals in this experiment be allowed to breed? If not, is breeding planned for later experiments or in the commercial phase?
- (ii) Are the arrangements for handling any offspring the same as those for the experimental animals? If not, please specify the arrangements.

- E4 (i) Is the embryo, product of the genetically engineered animal contained recombinant DNA expressed using the viral expression system?
- (ii) If so, with reference to question E4(i), what viral strain was the vector of the recombinant DNA?
- (iii) In relation to question E4(ii), please refer to question K1(iii).
- E5 (i) What new genetic materials inserted into the embryo (pro-nucleus stage)?
- (ii) What kind of product is expected from adult transgenic animal (at the proper age)?
- (iii) Is the transgenic animal and/or product of it expected for humans consumption?
- (iv) What the likelihood that these products will be dangerous to human beings and animals consuming these products? If so, explain.
- E6 (i) Is the transgenic animal fertile and capable of mating with its parents?
- (ii) Could the recombinant DNA used to develop transgenic animal be integrated to the genome of non-transgenic animal (existing in Indonesia) through mating?
- (iii) If so, what was the vector of the recombinant DNA?
- (iv) In relation to question E6(ii), please refer to question K1(iii).
- E7 (i) Is the new genetic material inserted into the embryo isolated from human gene encode certain useful protein?
- (ii) Is the protein produced by the transgenic animal will be used for medical treatment? If so, please refer to the provisions on the medical application concerned.
- (iii) In testing of the protein, please refer to question K10.
- E8 What management procedures and environmental factors, if any, are required for optimal expression of the introduced trait? Provide data to support your answer.

F FISH AND OTHER AQUATIC ORGANISMS

If the organism is to be consumed as a food, answer also the questions in Section J.

- F1 (i) Could the genetically engineered agricultural biotechnology products produce any 'new' metabolites or toxins likely to have deleterious effects on parasites or predators? If so, elaborate.
- (ii) What other unintended effects may result from the planned introduction? Your answer should include consideration of the effect of the genetically engineered agricultural biotechnology products on the community ecology at the site of the planned introduction.
- (iii) Are any of the likely gains directly linked to losses in other characteristics of the organisms?
- F2 (i) Will the genetically engineered agricultural biotechnology products in this introduction be allowed to breed? If not, is breeding planned for later introductions or commercial use?
- (ii) Are the arrangements for handling any offspring the same as those for the experimental organisms? If not, please specify the arrangements.
- F3 Can the changed or added genetic material be transmitted by means other than by reproduction normal for the species or to any other species? If so, specify, and elaborate its effects.
- F4 Do natural populations of the parental organism exist in Indonesia (including in rivers, lakes, or coastal waters)? If so, do the natural populations cause problems with other organisms? Specify the organisms and the problems.

- F5 If no natural populations of the organism to be modified exist in Indonesia, could the modified characteristics enhance the ability of the species to establish populations in aquatic habitats?
- F6 Has any experimental work been done on phenotypic expression of the introduced genetic material in naturally occurring organisms (e.g. cross-breeding of genetically engineered agricultural biotechnology products with wild/farmed stocks)? If so, what were the results?
- F7 What is the likelihood of the introduced genetic material entering the gene pool of natural populations?
- F8 Could the entry of the introduced genetic material into the gene pool of a natural organism have any effect on the distribution and abundance of the organism or on associated fisheries, the environment or public health? If so, please explain.
- F9 What mechanisms will be used to prevent dispersal of the genetically engineered agricultural biotechnology products into other ecosystems?

G INVERTEBRATES

If the organism is to be consumed as a food, answer also the questions in Section J.

- G1 (i) What effects might the genetically engineered agricultural biotechnology products have on the food chain?
- (ii) Could the genetically engineered agricultural biotechnology products produce any 'new' metabolites or toxins likely to have deleterious effects on parasites or predators? If so, elaborate.

- (iii) What other unintended effects may result from the introduction? Your answer should include consideration of the effect of the genetically engineered agricultural biotechnology products on the community ecology at the introduction site.
- G2
- (i) Will the genetically engineered agricultural biotechnology products in this introduction be fertile? If not, is it intended to use fertile organisms in later introductions?
 - (ii) Are the genotype and phenotype of the offspring the same as those of the genetically engineered agricultural biotechnology products to be introduced? If not, please specify the differences.
- G3
- Do populations of the parental organism exist in Indonesia? If so, do these populations cause agricultural, environmental or public health problems or benefits? Specify the problems or benefits.
- G4
- (i) Can the changed or added genetic material be transmitted by means other than reproduction normal for the species? If so, specify, and elaborate its effects.
 - (ii) What is the likelihood of the introduced genetic material entering gene pools of natural populations?
 - (iii) Can the changed or added genetic material be transmitted to any other species? If so, specify the mechanism of transfer and list the species.
- G5
- Has any experimental work been done on the phenotypic expression of the introduced genetic material in other genetic backgrounds (e.g. cross-breeding of modified strains with wild/caught stock)? If so, what were the results?
- G6
- Could the entry of the introduced genetic material into the gene pool of natural populations of the organism have any effect on the distribution and abundance of the natural populations? What would be the effect of this change?

- G7 What mechanisms will be used to prevent dispersal of the genetically engineered agricultural biotechnology products into other ecosystems?

H ORGANISMS FOR BIOLOGICAL CONTROL

- H1 (i) What is the species targeted for biological control?
(ii) What direct effects does the parent organism have on the target species?
(iii) What direct effects does the genetically engineered agricultural biotechnology products have on the target species?
- H2 (i) What is the host range of the genetically engineered agricultural biotechnology products? If the host range of the genetically engineered agricultural biotechnology products is likely to be different from that of the parent organism, explain why.
(ii) What non-target organisms have been tested for susceptibility to the genetically engineered agricultural biotechnology products?
(iii) What is the rationale for the choice of species tested?
- H3 Does the genetically engineered agricultural biotechnology products have a mechanism of self-elimination (e.g., infertility) that will limit its persistence in the environment? If not, please refer to question G7.
- H4 How is the genetically engineered agricultural biotechnology products transferred from one target individual to another and what factors affect this transferability?
- H5 What secondary effects can be envisaged on predators, prey or parasites of the target species?

- H6 (i) Explain the consequence of the removal or reduction of the target species on the management of agriculturally significant plants or farm animals.
- (ii) Predict any change in the ecosystem resulting from a reduction in the population of the target organism.
- H7 Does the genetically engineered agricultural biotechnology products produce metabolites which may have deleterious effects directly on other organisms or indirectly through concentration in the food chain? If so, elaborate.
- H8 If the modified genetic traits can be transmitted to other organisms which are likely to be in the environment (see A20), are these other organisms likely to affect non-target species?
- H9 What genetic response might be invoked in populations of the target organism as a result of the use of the genetically engineered agricultural biotechnology products (e.g. increased resistance to the modified organism)? What evidence is there for this response?

I ORGANISMS FOR BIOREMEDIATION

- I1 (i) What is the target substrate for bioremediation?
- (ii) What effect does the parent organism have on the target substrate?
- (iii) What effect does the genetically engineered agricultural biotechnology products have on the target substrate?
- I2 Describe natural strain variation of the parent organism that may be relevant to the assessment of the genetically engineered agricultural biotechnology products.

- I3 What other substances can be metabolized by the genetically engineered agricultural biotechnology products which cannot be metabolized by the parent organism?
- I4 Will the genetically engineered agricultural biotechnology products be self-sufficient once exposed to the target substrate or will additional measures be required (e.g. provision of supplementary nutrients and growth factors or other environmental modifications)?
- I5 Does the genetically engineered agricultural biotechnology products produce metabolites which may have deleterious effects directly on other organisms or indirectly through concentration in the food chain? If so, specify.
- I6 What effects might the genetically engineered agricultural biotechnology products have on water, air or soil quality?
- I7 What effects might the genetically engineered agricultural biotechnology products have on organisms which ingest it?
- I8 Will the genetically engineered agricultural biotechnology products be dispersed from the site of application? If so, describe the mechanisms involved and the possible/probable consequences.

J ORGANISMS TO BE CONSUMED AS FOOD

Please note that such products require clearance by the National Food Authority.

- J1 Is the parent organism or the donor organism already used in food production or eaten as food? If so, (i) at what consumption levels, and (ii) is any processing needed or commonly used before consumption?

- J2 (i) Does the genetically engineered agricultural biotechnology products produce metabolites which may have adverse effects on the consumer (humans or animals)? If so, elaborate. Provide available data on toxicology, allergenicity and other possible adverse effects.
- (ii) Can any products of the genetically engineered agricultural biotechnology products concentrate in the food chain to levels which may become toxic? If so, elaborate.
- J3 Will the nutritional quality of the food be changed by the genetic modification? If so, how?
- J4 Is the genetically engineered agricultural biotechnology products to be processed during the production of the food? If so, elaborate.

K MICROORGANISMS AS LIVE VACCINES FOR VETERINARY USE

In general vaccines can be divided into two groups, namely the active (living) and inactive (dead or sub-unit) vaccines. Living vaccine contains not only several useful antigen but also several unimportant materials that constitutes a part of the vaccine which may cause undesirable side effects. Recombinant DNA vaccine may also contain only synthetic protective antigen.

- K1 (i) What kind of vector to be used to develop vaccines?
- (ii) What vector strains to be used?
- (iii) State the physiological properties of the strains:
- (a) the natural habitat;
 - (b) growth requirements;
 - (c) reproduction mechanism;
 - (d) level of persistence to environment;

- (e) genetic information mechanism;
- (f) pathogenic and/or virulence.

- K2 What kind of recombinant vector containing genetically engineered agricultural biotechnology products? Refer to questions K1 (ii) and K1 (iii).
- K3 Could the vector act as a vaccine? If so, refer to questions K1 (ii) and K1 (iii).
- K4
- (i) What are the reasons for using vaccine?
 - (ii) What diseases to be controlled by vaccine?
 - (iii) What targeted pathogen would the vaccine be effective?
 - (iv) Is the vaccine used an active vaccine? If so, answer questions K5, K6, K7, K8, K9, K10, K11, and K12 in detail.
- K5
- (i) Is the genetic material of the vector capable of integrating with the DNA of the vaccinated animal?
 - (ii) Can the genetic material of the vector be transferred to other animal?
 - (iii) If the answer to questions (i) and (ii) is yes, please elaborate.
- K6
- (i) Can the genetically engineered active vaccine be found inside the vaccinated animals or within their feces or urine? If so, how long is it after the vaccination administered?
 - (ii) Is it possible that the genetically engineered active vaccine contaminate unvaccinated animal or normal species? If so, explain the mechanism of such contamination.
- K7
- (i) How long will the immunity last after the vaccination?
 - (ii) What is the level (titer) of vaccine is expected to reach the desired level of immunity?
 - (iii) Is booster dosage required?
 - (iv) How many times should the entire vaccine be given?

- (v) What is the purity level of the vaccine?
- K8 (i) Is the vaccine capable of transforming back into its pathogenic form?
(ii) If the vaccine injected to a pregnant animal, will the vaccine be transferred through the placenta?
(iii) If the vaccine injected to a pregnant animal, will the vaccine cause pathologic effects to the fetus in every stage of pregnancy?
If so, explain in detail.
- K9 (i) Does the vaccine belong to polyvalent vaccine? If so, explain in detail (its nature and characteristics).
(ii) Can the vaccine be administered right before another vaccine without causing negative effect on its effectiveness?
(iii) a)Would the vaccine neutralize the use of other vaccines given afterwards?
- K10 If experiment has to be conducted to test its safety, elaborate the methods used for the disposal of waste and the vaccinated animal (especially animal carrying the active vaccine tested).
- K11 If any, elaborate each method (chemical, physical and biological) to prevent the development or to eradicate the tested vaccine.
- K12 If the vaccine is applied to zoonotic diseases, describe the susceptible animal, including their age group and the geographical distribution of the diseases.

Evaluation on the Application for the Utilization of Genetically Engineered Agricultural Biotechnology Products.

Filling Sheet

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- I.
II. pnhangGeneral Guidance
-

Submission of Application

Filling sheet must be typed in black ink and enclosed at the front page of the application after being assessed by BTT. BTT has to send the application as well as filling sheet to BC completed with all relevant additional information (see question 14)

Test Utilization

At the end of the utilization, the applicant has to submit a complete report using the format at the relevant attachment of the provisions to the Department of Agriculture.

Confidential Trade Information

Part of the application containing that information must be referred clearly and the applicant has to provide enough reason to explain why that part must be treated as Company/Trade confidentiality.

Requirements Sheet for Sending Genetically Engineered Agricultural Biotechnology Products

The sending of Genetically Engineered Agricultural Biotechnology Products must fulfil the enclosed requirements.

Press Release

It is advisable that the applicant considers to announce his plans in the newspaper circulating in the planned utilization area, either about the time when the application is submitted or after receiving directives from the Department of Agriculture.

Approval

As soon as the approval is received from the authorized institution, a copy of the approval (such as license, registration number) has to be submitted to the Department of Agriculture.

Further Information

Please contact the Department of Agriculture.

See the Provisions on Biosafety of Genetically Engineered Agricultural Biotechnology Products for the requirements in detail.

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2. Assessment of proposed utilization of genetically engineered agricultural biotechnology products.

Cover Sheet

**Note: Where there is insufficient space on this form, please attach additional pages.*

1	Reference Number	BC numbers for small scale or large scale proposals previously submitted from which this planned release has developed	
2	Project Title		
3	Name of Organization		
4	Supervising BTT		
5	Project Supervisor or Manager		
	Name	Position	
	Address		
	Telephone Number		
6	Location of trial	7	Name of district or sub-district in which the release will take place
8	When is the release to occur on site?	9	When is work on site expected to end?
10	If this is a field trial, indicate scale (number of plants, size of plot, etc.)		
11	What is the size, scale and timing of anticipated future releases?		
	d		
12	What Government Authorities have been consulted about this Project? (List names of agencies and officers contacted)		

13 To which Authority(ies) should BC advice on the proposal be sent?
(Agencies which have legal responsibility for approving the end-use of the organism should be listed)

14 BTT Assessment:
(Give an evaluation of the Project including a comment on the Project Supervisor's capability to manage the work, the adequacy

<p>20 CEO (or delegate) to countersign:</p> <p>ir</p>	<p>Name of CEO (or delegate)</p>	
	<p>Signature of CEO (or delegate):</p>	<p>Date / /</p>

3. Requirements for transport of genetically engineered agricultural biotechnology products

General

Permit for transport of genetically engineered agricultural biotechnology products in the country, to or from foreign countries will be given by the authorized agency.

If the product is imported, it should: (i) meet the requirement of quarantine, (ii) accompanied by import document, and (iii) completed with transport document (including packing and labeling).

If the product to be exported, it should: (i) meet the requirement set by the importing country, (ii) agreement statement by the importer, (iii) completed with the transport document (including packing and labeling).

Transport document should contains the following information:

- ght Name and address of sender;
- ght Name and address of receiving party;
- ght Origin, name and taxonomy of the organism;
- ght Information of the inserted/changed characteristic and characteristic of donor organism;
- ght Summary of the risk assessment to the human health and environmental safety;
- ght Approximate date of transfer take place;
- ght The number and form of the organism/culture to be transferred.
- ght Other requirements needed for safety assurance of handling, storage, further transport, and its utilization;
- ght Control measures needed in case of accident;
- ght Purpose of organism utilization;
- ght Information related to the former utilization.

Packaging

1. Plants and their parts

- 1.1. Plant (if necessary in the pot) and its parts (except seed, cell and sub-cellular materials) should be carried out in a primary container (for example a plastic bag, strong paper envelop), which is packed in a secondary unbreakable container.
- 1.2. The outer container should be labeled to indicate the content, address (including telephone and fax numbers) of the responsible contact person, and the number of products.
- 1.3. Whole plant should be deflowered before transport, and the cut flower should be contained separately.
- 1.4. Plants should not be transported once they have set seed.

2. Seeds

- 2.1. Seeds should be carried out in a primary container (for example a plastic bag, strong paper envelop), which is packed in a secondary unbreakable container.
- 2.2. The outer container should be labeled to indicate the content, address (including telephone and fax numbers) of the responsible contact person, and the number of products.

3. Microorganisms, cells, or sub-cellular materials

- 3.1. Materials should be carried out in a leak proof primary container (for example test tube, bottle, etc.), which is packed in a secondary container containing absorbent material (for example, towel paper) enough to absorb the content of primary container if it breaks. Second container is placed in a wooden box or the like.
- 3.2. The outer container should be labeled to indicate the content, address (including telephone and fax numbers) of the responsible contact person, and the number of products.

4. Insect and the like

- 4.1. Insects (of any stadium) should be in unbreakable holding primary container, adequately sealed to prevent the escape of insects. The primary container should

be placed in well sealed secondary container made of styrofoam, and filled with filler to protect from shock. The second container should be future placed in wooden box and sealed.

- 4.2. The outer container should be labeled to indicate the content, address (including telephone and fax numbers) of the responsible contact person, and the number of products.

5. Animal

- 5.1. Animal should be placed in primary container made of wood, metal or crush proof materials, netted and sealed to prevent the escape of animals. The primary container should be placed in larger secondary container made of wood, metal, or other stronger material.
- 5.2. The outer container should be labeled to indicate the content, address (including telephone and fax numbers) of the responsible contact person, and the number of products.

REPORT OF BTT (BIOSAFETY TECHNICAL TEAM) ON THE UTILIZATION OF
GENETICALLY ENGINEERED AGRICULTURAL BIOTECHNOLOGY PRODUCTS

Name of Biosafety Technical Team:

No. of Biosafety Committee (BC) Project review:

Title of Project Applicant:

Licenses received from the Competent Authority (date):

Location of Utilization:

Date of starting:

Date of ending:

Summary of report.

Include the answers of these questions:

- What is the procedure of monitoring applied?
- Is the procedure following the protocol provided to be reviewed by the BC? Explain it.
- Is objective of the utilization achieved? Explain it.
- Does an unexpected effect occur? (In case that a harming effect occurs, a report shall be prepared and submitted to the Department of Agriculture and other related Entities during the occurrence of such event and rewritten in the final report).
- How many agricultural products with inserted character may endure at the outlet? How about the fate of agricultural products?
- Is this project to be continued to the next stage? Affirmatively, explain the detail.
- Do we know about potentiality of environmental and healthy risks?
- What steps will be taken in order to reduce or eliminate such potential risks?
- What is the procedure to be applied to evaluate environmental effect of the utilization?
- Is there any effect harming-damaging other agricultural products at the surrounding of place of utilization?

Signature of the Chairman of BTT

Date:

MODEL D FORM

Approval Letter on the Application for the Utilization of Genetically Engineered Agricultural Biotechnology Products

Number:

Attachment:

Subject: Approval of the Utilization To
of the Genetically Engineered
Agricultural Biotechnology
Products

Referring to your letter numberdated.....on the Application for the Utilization of Genetically Engineered agricultural Biotechnology Products, I herewith forward the following :

After reviewing the documents of your application consisted of:

- a. Deed of Establishment/Legal Legality
- b. Taxpayer Identification Number (NPWP)
- c. Data and the answers to the core questions
- d. Recommendation of the Biosafety Commission.

Considering the Article 39 para. 2 (a) of the Decree Of The Minister Of Agriculture Number: 85/Kpts/HK.330/9/1997 On The Provisions On Biosafety Of Genetically Engineered Agricultural Biotechnology Products, we decide to approve your application for the utilization of the genetically engineered agricultural biotechnology products.

Please be informed and we thank you for your attention.

The Related Director General/Director
General of the Agency for Agricultural
Research and Development

Cc to:

1. Minister of Agriculture (as a report)
2. Biosafety Commission

MODEL E FORM

Letter of Denial of the Application for the Utilization of Genetically Engineered Agricultural Biotechnology Products

Number:

Attachment:

Subject: Denial of the Utilization To
of Genetically Engineered
Agricultural Biotechnology
Products

Referring to your letter numberdated.....on the Application for the Utilization of Genetically Engineered agricultural Biotechnology Products, I herewith inform you that on the basis of the Article 39 para. 2 (b) of the Decree of The Minister of Agriculture Number: 85/Kpts/HK.330/9/1997 on the Provisions on Biosafety of Genetically Engineered Agricultural Biotechnology Products, we regret to deny your application for the following reasons:

- 1.
- 2.
- 3.
- 4.

Please be informed and we thank you for your attention.

The Related Director General/Director
General of the Agency for Agricultural
Research And Development

Cc to:

1. Minister of Agriculture (as a report)
2. Biosafety Commission