

THE MINISTER OF AGRICULTURE
THE MINISTER OF FORESTRY AND ESTATE CROPS
THE MINISTER OF HEALTH
THE STATE MINISTER OF FOOD AND HORTICULTURE

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**JOINT DECREE OF
THE MINISTER OF AGRICULTURE, THE MINISTER OF FORESTRY AND
ESTATE CROPS, THE MINISTER OF HEALTH, AND THE STATE
MINISTER OF FOOD AND HORTICULTURE**

Number: 998.1/Kpts/OT.210/9/99
790.a/Kpts-IX/1999
1145A/MENKES/SKB/IX/199
015A/NmenegPHOR/09/1999

CONCERNING

**BIOSAFETY AND FOOD SAFETY OF GENETICALLY ENGINEERED
AGRICULTURAL PRODUCTS**

THE MINISTER OF AGRICULTURE
THE MINISTER OF FORESTRY AND ESTATE CROPS
THE MINISTER OF HEALTH
THE STATE MINISTER OF FOOD AND HORTICULTURE

- Considering that:
- a. rapid development of biotechnology through genetic engineering, made it possible to modify a certain trait of organism by utilizing an exogenous gene, according to market demand;
 - b. genetically engineered agricultural products could give a large benefit, however precautionary and careful approach are needed in order the possibility of being harmful to biodiversity, environment, and humans could be avoided;
 - c. the provisions of the laws and regulations in effect do not sufficiently regulate biosafety and food safety of genetically engineered agricultural products;
 - d. based on of the above mentioned matters, it is considered necessary to state the provisions on biosafety and food safety of genetically engineered agricultural products in a Joint Decree of the Minister of Agriculture, the Minister of Forestry and Estate Crops, the Minister of Health, and the State Minister of Food and Horticulture.

- Bearing in mind:
1. The Republic of Indonesia Law Number 6 year 1967 concerning Basis of Animal Husbandry and Animal Health/Veterinarian (Juncto State Gazette year 1967; Number 10, Additional State Gazette Number 2824);
 2. The Republic of Indonesia Law Number 9 year 1985 concerning Fishery (Juncto State Gazette year 1985; Number 46, Additional State Gazette Number 3299);
 3. The Republic of Indonesia Law Number 12 year 1992 concerning Crops Cultivation System (Juncto State Gazette year 1992; Number 46, Additional State Gazette Number 3478);

4. The Republic of Indonesia Law Number 16 year 1992 concerning Animal, Fish, and Plant Quarantine (Juncto State Gazette year 1992; Number 56, Additional State Gazette Number 3482);
5. The Republic of Indonesia Law Number 23 year 1992 concerning Health (Juncto State Gazette year 1992; Number 100, Additional State Gazette Number 3495);
6. The Republic of Indonesia Law Number 5 of 1994 Concerning United Nations Convention on Biological Diversity (Juncto State Gazette year 1994; Number 41, Additional State Gazette Number 3556);
7. The Republic of Indonesia Law Number 7 of 1996 concerning Food (Juncto State Gazette year 1996; Number 99, Additional State Gazette Number 3656);
8. Government Regulation of the Republic of Indonesia Number 15 year 1977 concerning Rejection, Prevention, Eradication, and Animal Disease Treatment (Juncto State Gazette year 1977; Number 20, Additional State Gazette Number 3101);
9. Government Regulation of the Republic of Indonesia Number 16 year 1977 concerning Business of Animal Husbandry (Juncto State Gazette year 1977; Number 21, Additional State Gazette Number 3408));
10. Government Regulation of the Republic of Indonesia Number 22 year 1983 concerning Veterinary Public Health (Juncto State Gazette year 1983; Number 28, Additional State Gazette Number 3253);
11. Government Regulation of the Republic of Indonesia Number 15 year 1990 concerning Fishery Business (Juncto State Gazette year 1990; Number 19, Additional State Gazette Number 3408);
12. Government Regulation of the Republic of Indonesia Number 78 year 1992 concerning Animal Medicine (Juncto State Gazette

- year 1992; Number 129, Additional State Gazette Number 3509);
13. Government Regulation of the Republic of Indonesia Number 6 year 1995 concerning Plant Protection (Juncto State Gazette year 1995; Number 12, Additional State Gazette Number 3586);
 14. Government Regulation of the Republic of Indonesia Number 44 year 1995 concerning Plant Seeds (Juncto State Gazette year 1995; Number 85, Additional State Gazette Number 3616);
 15. Decree of the President of the Republic of Indonesia Number 69 year 1999 concerning Label and Foods Ad (Juncto State Gazette year 1999; Number 131, Additional State Gazette Number 3867);
 16. Decree of the President of the Republic of Indonesia Number 44 year 1974 concerning the Basis of the Departmental Organization;
 17. Decree of the Minister of Agriculture Number 61 year 1998 concerning Position, Duty, Organization Structure, and Working System of the Department;
 18. Decree of the President of the Republic of Indonesia Number 101 year 1998 concerning Position, Function, Organization Structure, and Working System of the State Minister;
 19. Decree of the President of the Republic of Indonesia Number 122/M year 1998 concerning Development Reformation Cabinet;
 20. Decree of the Minister of Forestry and Estate Crops Number 243/Kpts-II/1999 concerning Organization and the Working System of Forestry and Estate Crops Department;
 21. Regulation of the Minister of Health Number 329/MENKES/PER/XII/1976 concerning Production and Distribution of Foods;
 22. Decree of the Minister of Agriculture Number

- 280/Kpts/Um/8/1977 concerning Procedure for Application and Registration of Pesticides;
23. Decree of the Minister of Agriculture Number 476/Kpts/Um/8/1977 concerning Procedure Requirements to Release Variety;
 24. Regulation of the Minister of Health Number 23/MENKES/SK/I/1978 concerning Guidelines for the Best Way How to Produce Good Foods;
 25. Regulation of the Minister of Health Number 558/MENKES/SK/1984 concerning Organization and the Working System of Health Department;
 26. Regulation of the Minister of Health Number 722/MENKES/PER/IX/1988 concerning Food Additives
 27. Regulation of the Minister of Health Number 382/MENKES/PER/VI/ 1989 concerning Food Registration;
 28. Decree of the Minister of Agriculture Number 695/Kpts/TN.200/8/1996 concerning Requirements and Registration Procedure and Testing of Animal Medicine Quality;
 29. Decree of the Minister of Agriculture Number 411/Kpts/TP.120/6/1995 concerning the Importation of Bio Agent into the Territory of the Republic of Indonesia;
 30. Decree of the Minister of Agriculture Number 1016/Kpts/OT.210/12/1998 concerning the Organization and the Working System of Agriculture Department;
 31. Decree of the State Minister of Food and Horticulture Number Kep-05/M/7/1998 concerning the Organization and the Working System of Staff of the State Minister of Food and Horticulture.

DECIDES

To State: THE JOINT DECREE OF THE MINISTER OF AGRICULTURE, THE
MINISTER OF FORESTRY AND ESTATE CROPS, THE MINISTER OF

HEALTH, AND THE STATE MINISTER OF FOOD AND
HORTICULTURE CONCERNING BIOSAFETY AND FOOD SAFETY
OF GENETICALLY ENGINEERED AGRICULTURAL PRODUCTS.

CHAPTER I

GENERAL PROVISIONS

Article 1

In this Joint Decree referred to as:

1. Genetically engineered agricultural products, which are hereinafter abbreviated to GEAP, are transgenic animals, materials originating from transgenic animals, and processed products of transgenic animals, transgenic fish, materials originating from transgenic fish, and processed products of transgenic fish, transgenic plants and their parts, and processed products of transgenic plants, and transgenic microorganisms.
2. Biosafety is the condition and efforts that are needed to prevent GEAP could cause possible risks for disturbance, harm and/or endanger biodiversity (including animal, fish and plants) and the environment.
3. Food safety is the condition and efforts that are needed in the production, storage, distribution and preparation processes of GEAP to prevent possible risks for GEAP could cause disturbance, harm and/or endanger human health.
4. Utilization of GEAP comprise of the development of scientific knowledge, research, breeding, production, distribution including trade, and utilization.
5. Genetic engineering, are all efforts to carry out a deliberate change to the genome of living creatures by adding, deleting and/or changing the original structure of the genome by using recombinant DNA technology.
6. Genome is the total genetic complement of an organism.
7. Deoxyribose Nucleic Acid, which is hereinafter called DNA, is a molecule carries genetic information of most organisms, which consists of four bases and phosphate sugar as a backbone.

8. Recombinant DNA is a combination of DNA, which is formed of the *in vitro* development of DNA fragments of two organism's species.
9. Transgenic animals are all genetically engineered animals, which live on land, either cultivated or wild life.
10. Materials originating from transgenic animals are materials originating from genetically engineered animals, which could be further processed such as meat, milk, eggs, feathers, hairs, wool, horns, nails, skins, bones, sperm, and honey.
11. Processed products of transgenic animals are food derived from materials originating from transgenic animals, which are processed by such a way or a method with or without food additive.
12. Transgenic fish species include all other genetically engineered aquatic species, which are hereinafter called transgenic fish, are pisces, crustacean, mollusc, coelenterates, echinoderms, amphibians, reptiles, mammals, and algae.
13. Materials originating from transgenic fish are materials originating from genetically engineered fish, which could be further processed such as oil and skin of fish.
14. Processed products of transgenic fish are food derived from materials originating from transgenic fish, which are processed by such a way or a method with or without food additive.
15. Transgenic plants include genetically engineered annual plants, genetically engineered perennial plants, and their parts.
16. Processed products of transgenic plants are food derived from materials originating from transgenic plants, which are processed by such a way or a method with or without food additive.
17. Transgenic microorganisms include genetically engineered virus, bacteria protozoa, yeast, fungi, and micro algae.
18. Substantially equivalent is the condition of food products derived from GEAP, substantially equal to its original non transgenic organisms, except the engineered trait.

19. Generally regarded as safe (GRAS) is the safety condition, which applied to food additive and food products derived from GEAP, to be consumed.
20. Biosafety and Food Safety Committee, which is hereinafter abbreviated to BFSC, is the committee with the tasks of providing assistance to the Minister of Agriculture, the Minister of Forestry and Estate Crops, the Minister of Health, and the State Minister of Food and Horticulture in compilation and establishment of biosafety and food safety policy in the utilization of GEAP.
21. Biosafety and Food Safety Technical Team, which is hereinafter abbreviated to BFSTT, is the team with the task of providing assistance the BFSC in evaluation and risk assessment of biosafety and food safety, and appropriateness of GEAP utilization.

Article 2

- (1) This decree is intended to regulate and supervise biosafety and food safety of the GEAP utilization.
- (2) The purpose of this decree is to ensure the biosafety and food safety for human health, biodiversity (include animals, fish, and plants), and the environment in relation to the utilization of GEAP.

Article 3

The scope of this decree covers the regulation of kinds, requirements, procedure, rights and obligations, monitoring, controlling, and reporting of biosafety and food safety of the utilization of GEAP.

CHAPTER II

KINDS AND UTILIZATION OF THE GEAP

First Part

Kinds of the GEAP

Article 4

(1) Kinds of GEAP include:

- a. Transgenic animals, materials originating from them and their processed products;
- b. Transgenic fish, materials originating from them and their processed products;
- c. Transgenic plants, their parts and their processed products; and
- d. Transgenic microorganisms.

(1) Transgenic animals comprise various types of genetically engineered animals such as livestock and poultry, pet animals, animals for pests control, laboratory animals, and materials originating from transgenic animals and their processed products.

(2) Transgenic fish comprise various types of genetically engineered fish such as cultivated fish, pet fish, and laboratory fish, and materials originating from transgenic fish and their processed products.

(3) Transgenic plants and their parts comprise various types of genetically engineered crops such as food crops, horticultural crops, industrial and estate crops, forest crops, and their processed products.

(4) Transgenic microorganisms comprise various types of genetically engineered microorganisms such as antagonistic microorganisms, nutrient fixing microorganisms, microorganisms for catalytic production, microorganisms for mediator, and microorganisms for degradation.

Second Part

Utilization of Transgenic Animals, Materials Originating from Them and Their Processed Products

Article 5

- (1) Transgenic livestock and poultry as referred to Article 4 paragraph (2) are used as food and feed stuffs, and industrial raw material.
- (2) Transgenic pet animals as referred to Article 4 paragraph (2) are used as hobby and sports.
- (3) Transgenic laboratory animals as referred to Article 4 paragraph (2) are used as scientific and technological tool, and for pest control.
- (4) Transgenic animals for pest control as referred to Article 4 paragraph (2) are used to control plant pest organisms.
- (5) Materials originating from transgenic animals as referred to Article 4 paragraph (2) are used as food and feed stuffs, industrial raw material, and material for animal drugs, and materials for controlling microorganisms.
- (6) Processed products of transgenic animals as referred to Article 4 paragraph (2) are used as food and feed stuffs.

Third Part

Utilization of Transgenic Fish, Materials Originating from Them and Their Processed Products

Article 6

- (1) Transgenic cultivated fish as referred to Article 4 paragraph (3) are used as food and feed stuff, and industrial raw materials.
- (2) Transgenic pet fish as referred to Article 4 paragraph (3) are used as hobby, handicraft, decoration, etc.
- (3) Transgenic laboratory fish as referred to Article 4 paragraph (3) are used as technological tools for pests control and science.
- (4) Materials originating from transgenic fish as referred to Article 4 paragraph (3) are used as food and feed stuff, and industrial raw materials.

- (5) Processed products of transgenic fish as referred to Article 4 paragraph (3) are used as food and feed stuffs.

Fourth Part

Utilization of Transgenic Plants, Their Parts, and Their Processed Products

Article 7

- (1) Transgenic plants as referred to Article 4 paragraph (4) are used as food and feed stuff.
- (2) Transgenic plants as referred to Article 4 paragraph (4) are used as medical ingredient
- (3) Transgenic plants as referred to Article 4 paragraph (4) are used as biological control agent.
- (4) Transgenic plants as referred to Article 4 paragraph (4) are used as bio-fertilizer and bio-remediation.
- (5) Transgenic plants as referred to Article 4 paragraph (4) are used as industrial raw materials.
- (6) Transgenic plants as referred to Article 4 paragraph (4) are used as ornamental plants.
- (7) Processed products of transgenic plants as referred to Article 4 paragraph (4) are used as food and feed stuffs.

Fifth Part

Utilization of Transgenic Microorganisms

Article 8

- (1) Transgenic microorganisms as referred Article 4 paragraph (5) are used as food and feed production processes.
- (2) Transgenic microorganisms as referred Article 4 paragraph (5) are used as food and feed

- (3) Transgenic microorganisms as referred Article 4 paragraph (5) are used as bio-fertilizer, bio-pesticide and bio-herbicide, and other production inputs.
- (4) Transgenic microorganisms as referred Article 4 paragraph (5) are used as processed side products, and or agricultural wastes, and bio-remediation.
- (5) Transgenic microorganisms as referred Article 4 paragraph (5) are used as animal vaccine and animal concealed vaccine.
- (6) Transgenic microorganisms as referred Article 4 paragraph (5) are used as antisera, probiotic, and biological materials for animals.

CHAPTER III

REQUIREMENTS OF BIOSAFETY AND FOOD SAFETY OF GEAP

First Part

General

Article 9

The utilization of GEAP originating from both domestic and foreign products must pay attention to and take into consideration the religious, ethical, socio-cultural and esthetical norms.

Second Part

Requirement of Transgenic Animals, Materials Originating from Them and Their Processed Products

Article 10

Assessment of biosafety and food safety of transgenic animals, materials originating from them, and their processed products must fulfill the following requirements:

- a. the genus name, species, and the animal line;
- b. the modification methods used in the process of engineering transgenic animals;
- c. when a vector is used in the genetic modification, the vector used must not be a pathogen organism either for human beings or other organisms;

- d. complete information on the source of the genes used and the method of destruction of the remaining vector;
- e. the genetic modification attempts carried out will not cause a change in animal behavior;
- 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. information concerning the reproduction performance of transgenic animal (fertile or infertile) needs 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;
- h. information on the method of eradication in case of the unwanted deviation;
- i. the kind of feed, ability to feed, and the manner of feeding.

Article 11

Aside from the requirements as referred to Article 10, for transgenic animals used for food and feed stuff, and industrial raw material, must also be accompanied by the following information:

- a. stability of insert gene and gene efficacy;
- b. nutritional quality/value;
- c. natural or modified toxic compound, anti nutrition and allergen;
- d. to fulfill the requirements of substantially equivalent;
- e. generally regarded as safe to be consumed;
- f. molecular characterization and stability of genetic modification carried out;
- g. expression, function and effect of genetic modification;
- h. possible change on ecosystem of soil, water, and biological resources that might take place.

Article 12

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

- a. stability of insert gene and gene efficacy;
- b. natural or modified toxic compound, anti nutrition and allergen;
- c. molecular characterization and stability of genetic modification carried out;
- d. expression, function and effect of genetic modification;
- e. possible change on ecosystem of soil, water, and biological resources that might take place.

Article 13

Aside from the requirements as referred to Article 10, for transgenic laboratory animals used for experiment, scientific and technological tool, and for disease control, must also be accompanied by the following information:

- a. stability of insert gene and gene efficacy;
- b. targeted organism;
- c. expression, function and effect of genetic modification;
- d. possible change on ecosystem of soil, water, and biological resources that might take place.

Article 14

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

- a. stability of insert gene and gene efficacy;
- b. nutritional quality/value;
- c. natural or modified toxic compound, anti nutrition and allergen;
- d. to fulfill the requirements of substantially equivalent;
- e. generally regarded as safe to be consumed;
- f. molecular characterization and stability of genetic modification carried out;
- g. expression, function and effect of genetic modification.

Article 15

Aside from the requirements as referred to Article 10, for processed products of transgenic animals, must also be accompanied by the following information:

- a. nutritional quality/value;
- b. natural or modified toxic compound, anti nutrition and allergen;
- c. to fulfill the requirements of substantially equivalent;
- d. generally regarded as safe to be consumed.

Third Part

Requirement of Transgenic Fish, Materials Originating from Them and Their Processed Products

Article 16

Assessment of biosafety and food safety of transgenic fish, materials originating from them, and their processed products must fulfill the following requirements:

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

- h. information on the method of eradication in case of the unwanted deviation;
- i. the kind of feed, and the manner of feeding.

Article 17

Aside from the requirements as referred to Article 16, for transgenic fish used for food and feed stuff, and industrial raw material, must also be accompanied by the following information:

- a. stability of insert gene and gene efficacy;
- b. nutritional quality/value;
- c. natural or modified toxic compound, anti nutrition and allergen;
- d. to fulfill the requirements of substantially equivalent;
- e. generally regarded as safe to be consumed;
- f. molecular characterization and stability of genetic modification carried out;
- g. expression, function and effect of genetic modification;
- h. possible change on ecosystem of soil, water, and biological resources that might take place.

Article 18

Aside from the requirements as referred to Article 16, for transgenic pet fish used for as hobby, handicraft, decoration, and other need, the following information must also be given:

- a. stability of insert gene and gene efficacy;
- b. natural or modified toxic compound, anti nutrition and allergen;
- c. molecular characterization and stability of genetic modification carried out;
- d. expression, function and effect of genetic modification;
- e. possible change on ecosystem of soil, water, and biological resources that might take place.

Article 19

Aside from the requirements as referred to Article 16, for transgenic laboratory fish used for disease control tools, and science, must also be accompanied by the following information:

- e. stability of insert gene and gene efficacy;
- f. targeted organism;
- g. expression, function and effect of genetic modification;
- h. possible change on ecosystem of soil, water, and biological resources that might take place.

Article 20

Aside from the requirements as referred to Article 16, for materials originating from transgenic fish used for food and feed stuff, industrial raw material, must also be accompanied by the following information:

- h. stability of insert gene and gene efficacy;
- i. nutritional quality/value;
- j. natural or modified toxic compound, anti nutrition and allergen;
- k. to fulfill the requirements of substantially equivalent;
- l. generally regarded as safe to be consumed;
- m. molecular characterization and stability of genetic modification carried out;
- n. expression, function and effect of genetic modification.

Article 21

Aside from the requirements as referred to Article 16, for processed products of transgenic fish used for food and feed stuff, must also be accompanied by the following information:

- e. nutritional quality/value;
- f. natural or modified toxic compound, anti nutrition and allergen;
- g. to fulfill the requirements of substantially equivalent;
- h. generally regarded as safe to be consumed.

Fourth Part

Requirement of Transgenic Plants, Their Parts, and Their Processed Products

Article 22

Assessment of biosafety and food safety of transgenic plants, their parts, and their processed products must fulfill the following requirements:

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

Article 23

Aside from the requirements as referred to Article 22, for transgenic plants used for food and feed stuff, must also be accompanied by the following information:

- a. stability of insert gene and gene efficacy;
- b. nutritional quality/value;
- c. natural or modified toxic compound, anti nutrition and allergen;
- d. to fulfill the requirements of substantially equivalent;
- e. generally regarded as safe to be consumed;
- f. possibility of cross breeding with wild relative;
- g. possibility of the development of resistance to plant pests or herbicide of non target species through out-crossing;

- h. expression, function and effect of genetic modification.

Article 24

Aside from the requirements as referred to Article 22, for transgenic plants and their processed products used for medical ingredients, must also be accompanied by the following information:

- a. stability of insert gene and gene efficacy;
- b. molecular characterization and stability of genetic modification carried out;
- c. certain chemical ingredient including the possible efficacy and side effects (toxicity);
- d. natural or modified toxic compound, anti nutrition and allergen;
- e. to fulfill the requirements of substantially equivalent;
- f. generally regarded as safe to be consumed;
- g. possibility of cross breeding with wild relative;
- h. possibility of the development of resistance to plant pests or herbicide of non target species through out-crossing.

Article 25

Aside from the requirements as referred to Article 22, 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. possibility of cross breeding with wild relative;
- d. molecular characterization and stability of genetic modification carried out;
- e. possible change on ecosystem of soil, water, and biological resources that might take place.

Article 26

Aside from the requirements as referred to Article 22, for transgenic plants used for bio-fertilizer and bio-remediation must also be accompanied by the following information:

- a. stability of insert gene and gene efficacy;
- b. targeted organisms;
- c. possibility of cross breeding with wild relative;
- d. molecular characterization and stability of genetic modification carried out;
- e. possible change on ecosystem of soil, water, and biological resources that might take place.

Article 27

Aside from the requirements as referred to Article 22, for transgenic plants used for industrial raw materials must also be accompanied by the following information:

- a. stability of insert gene and gene efficacy;
- b. natural or modified toxic compound, anti nutrition and allergen;
- c. possibility of cross breeding with wild relative;
- d. molecular characterization and stability of genetic modification carried out;
- e. possible change on ecosystem of soil, water, and biological resources that might take place.

Article 28

Aside from the requirements as referred to Article 22, for transgenic plants used for ornamental plants, must also be accompanied by the following information:

- a. stability of insert gene and gene efficacy;
- b. natural or modified toxic compound, anti nutrition and allergen;
- c. possibility of cross breeding with wild relative;
- d. molecular characterization and stability of genetic modification carried out;
- e. possible change on ecosystem of soil, water, and biological resources that might take place.

Article 29

Aside from the requirements as referred to Article 22, for processed products of transgenic plants, must also be accompanied by the following information:

- a. nutritional quality/value;

- b. natural or modified toxic compound, anti nutrition and allergen;
- c. to fulfill the requirements of substantially equivalent;
- d. generally regarded as safe to be consumed.

Fifth Part

Requirement of Transgenic Microorganisms

Article 30

Assessment of biosafety and food safety of transgenic microorganisms must fulfill the following requirements:

- a. genus and origin of parent microorganism, microorganisms source of insert, and microorganisms source of vector;
- b. the modification methods used in the process of engineering transgenic microorganisms;
- c. when a vector is used in the genetic modification, the vector used must not be a pathogen organism either for human beings or other organisms;
- d. presence of wild relative of parents microorganism as well as microorganisms source of vector;
- e. method of eradication in case of the unwanted deviation;
- f. complete information on the source of the genes used and the method of destruction of the remaining vector;
- g. information on the method of eradication in case of the unwanted deviation.

Article 31

Aside from the requirements referred to Article 30, for transgenic microorganisms used for industrial process for food and feed must also be accompanied by the following information:

- a. stability of insert gene and gene efficacy;
- 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. to fulfill the requirements of substantially equivalent;
- f. generally regarded as safe to be consumed;
- g. molecular characterization and stability of genetic modification carried out.

Article 32

Aside from the requirements referred to Article 30, for transgenic microorganisms used for food and feed, must also be accompanied by the following information:

- a. stability of insert gene and gene efficacy;
- b. kind of feed or material, method of processing and the quality of material after processing; and/or
- c. kind of food, method of processing before consumption, and the quality of food after processing;
- d. natural or modified ingredients of toxic compound, anti nutrition, and allergen;
- e. to fulfill the requirements of substantially equivalent;
- f. generally regarded as safe to be consumed;
- g. molecular characterization and stability of genetic modification carried out.

Article 33

Aside from the requirements referred to Article 30, for transgenic microorganisms used for fertilizer, pesticide, and other production inputs, must also be accompanied by the following information:

- a. stability of insert gene and gene efficacy;
- b. mechanism of microbe activities as production inputs;
- c. natural or modified ingredients of toxic compound, anti nutrition, and allergen;
- d. molecular characterization and stability of genetic modification carried out;
- e. information on targeted plants.

Article 34

Aside from the requirements referred to Article 30, 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. stability of insert gene and gene efficacy;
- b. type and mechanism of microbe activities and the nature of the side products including the liquid, solid and gas physical characteristics;
- c. molecular characterization and stability of genetic modification carried out;
- d. possible change on ecosystem of soil, water, and biological resources that might take place.

Article 35

Aside from the requirements referred to Article 30, for transgenic microorganisms used for animal 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 36

Aside from the requirements referred to Article 30, for transgenic microorganisms used for antisera, probiotic, and biological material, 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. impacts of the administration of antisera, probiotic, and biological material which is administered to livestock on human beings.

CHAPTER IV

PROCEDURE FOR ASSESSMENT OF BIOSAFETY AND FOOD SAFETY OF GEAP

First Part

Application

Article 37

- (1) Every person or legal entity who will utilize GEAP must file a written application for assessment of biosafety and food safety by using “model a” form to:
- a. The Minister of Agriculture in this case the Director General of Animal Husbandry for transgenic animals, materials originating from transgenic animals, vaccine culture, antisera, 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 transgenic fish, vaccine culture, antisera, probiotic, and biological material for transgenic fish;
 - 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, bio-fertilizer, and biological materials for plants;
 - d. The Minister of Health in this case the Director General of Drug and Food Inspection for processed products from transgenic animals, fish, and plants, and transgenic microorganisms used for materials and food production process;
 - e. The Minister of Forestry and Estate Crops in this case the Director General of Estate Crops for transgenic estate crops and industrial crops as well as their parts;
 - f. The Minister of Forestry and Estate Crops in this case the Director General of Reboisation and Land Rehabilitation for transgenic forest crops;
 - g. The Minister of Agriculture in this case the Director of the Center of Quarantine for microorganisms of the transgenic biological agents;

- h. The Minister of Agriculture in this case the Pesticide Committee for microorganisms of the transgenic pesticides;
- (2) The application referred to the paragraph (1) must be accompanied by the requirements in line with the kind of GEAP as mentioned in Chapter II and Chapter III of this Joint Decree.

Article 38

- (1) The official as referred to in Article 37 after receiving the application, requests the considerations on the technical aspects of biosafety and food safety of GEAP to the BFSC.
- (2) After perusing the application referred to paragraph (1), the BFSC requests the BFSTT for evaluation and technical assessment on biosafety and food safety of GEAP.
- (3) After evaluation and technical assessment on biosafety and food safety of GEAP as referred to paragraph (2), the BFSTT is obligated to submit a report on the results of evaluation and technical assessment on biosafety and food safety of GEAP to BFSC.
- (4) Based on the report on the results of evaluation and technical assessment on biosafety and food safety of GEAP, the BFSC submit its suggestions/considerations or recommendations concerning biosafety and/or food safety of GEAP to the official as referred to Article 37 paragraph (1).

Article 39

- (1) The composition of membership, duties, and responsibilities of the BFSC found in the Attachment I of this Joint Decree.
- (2) The composition of membership, duties, and responsibilities of the BFSTT shall be determined with a separate decree by the Chairman of the BFSC.

Second Part

Assessment

Article 40

- (1) The evaluation and technical assessment on biosafety and food safety of GEAP by BFSTT for conducting evaluation of the application as referred to Article 38 paragraph (2) and paragraph (3) is done by using “model b” form.
- (2) When BFSTT still requires further assessment through a laboratory, greenhouse, and confined field test, the applicant is requested to send a sample of the GEAP to the BFSTT by complying with the requirements as referred to in the “model b” form.
- (3) The expenses for evaluation and technical assessment, and the laboratory, greenhouse, and confined 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) and paragraph (2) by the BFSTT shall be manifested in a report using the “model c” form.
- (5) Further provisions on the procedure of assessment shall be determined by the Director General of the Agency for Agricultural Research and Development, Director General of the Agency for Forestry and Estate Crops Research and Development, and Director General of Directorate General of Drug and Food Inspection as Chairman of the BFSC.

Third Part

Issuance of Recommendation

Article 41

- (1) The report on the results of technical assessment of biosafety and food safety of the BFSTT as referred to Article 38 paragraph (3) and Article 40 paragraph (4) shall be used as a consideration by the BFSC to give a recommendation to the official as referred to Article 37 paragraph (1) by using “model d” form.
- (2) The recommendation of BFSC concerning safe or not safe as referred to paragraph

(1) shall be used by the official as referred to Article 37 paragraph (1) as the basis for the determination of GEAP utilization.

CHAPTER V

RIGHTS AND OBLIGATIONS

Article 42

- (1) Any person or legal entity who or which has obtained approval for the utilization of GEAP is entitled to obtain a protection for the secrecy of its GEAP, particularly with regard to the technology and 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 document for the utilization of GEAP which must be carried out by the official as referred to Article 37 paragraph (1), BFSC and BFSTT.

Article 43

When the GEAP causes biosafety and food safety harm, then in that case the person or legal entity who or which has obtained approval for the utilization of the GEAP is obligated to participate in the control and overcoming.

CHAPTER VI

MONITORING, MANAGING AND REPORTING

Article 44

Any person or legal entity who or which has obtained approval for the utilization of GEAP is obligated to submit a periodical report once every 12 (twelve) months or any time when required in the event of biosafety and food safety harm, to the official as referred to the Article 37 paragraph (1) in line with the kind of GEAP.

Article 45

- (1) In order to observe the utilization of GEAP monitoring and managing shall be carried out by the official as referred to Article 37 paragraph (1).
- (2) In the implementation of monitoring and managing of the utilization of GEAP, the official as referred to Article 37 paragraph (1) is assisted by:
 - a. Animal Drugs Supervisor, Pest and Disease Observer, Animal Stock Supervisor, Veterinarian assigned to the Animal Slaughterhouse/Poultry Slaughterhouse, Animal Feed Supervisor, Animal Quarantine Supervisor for transgenic animals and materials originating from them;
 - b. Fish Resources Supervisor and Fish Quarantine Supervisor for transgenic fish and materials originating from it;
 - c. Pests and Plant Diseases Observer, Seed Supervisor, Fertilizer Supervisor, Pesticide Supervisor, and Plant Quarantine Supervisor for transgenic plants and their parts, and transgenic microorganisms;
 - d. Food Supervisor for transgenic animal, fish, and plant processing products, and transgenic microorganism which are used as food material and food production processing.
- (3) Evaluation and assessment of biosafety and food safety due to the utilization of GEAP are conducted by BFSC with BFSTT assistance.
- (4) BFSC provide recommendation concerning biosafety and food safety due to the utilization of GEAP to the official as referred to Article 37 paragraph (1).
- (5) The supervising and managing mechanisms due to the utilization of GEAP will be decided later on by the Minister of Agriculture, the Minister of Forestry and Estate Crops, the Minister of Health, and the State Minister of Food and Horticulture according to their task.

CHAPTER VII

TRANSITIONAL PROVISIONS

Article 46

- (1) Any person or legal entity who or which has utilized GEAP prior the enforcement of this Joint Decree, at the latest within 12 (twelve) months as of entry into force of this Decree, must file an application on the basis of this Joint Decree.
- (2) When the rule as referred to paragraph (1) is ignored, then the Party who utilized the GEAP subject to sanction according to laws and regulations in effect.

CHAPTER VIII

CLOSING PROVISIONS

Article 47

- (1) This Joint Decree is without prejudice to the validity of the Decree of the Minister of Agriculture, the Minister of Forestry and Estate Crops, the Minister of Health, and the State Minister of Food and Horticulture 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. Production and distribution of food;
 - e. Guidelines of good methods for food production;
 - f. Food additive;
 - g. Food registration.
- (1) By entering into force of this Joint Decree, the Decree of the Minister of Agriculture Number 856/Kpts/KH330/9/1997 concerning the Provisions on Biosafety of Genetically Engineered Agricultural Biotechnology Products is herewith declared void.

Article 48

This Joint Decree enters into force on the date it is decided.

Decided in: Jakarta
on September 29, 1992

MINISTER OF AGRICULTURE

MINISTER OF FORESTRY AND ESTATE CROPS

SOLEH SOLAHUDDIN

MUSLIMIN NASUTION

MINISTER OF HEALTH

STATE MINISTER OF FOOD AND HORTICULTURE

F. A. MOELOEK

A. M. SAEFUDDIN

A copy of this Decree is submitted to:

1. State Minister of National Planning Development/Head of Bappenas;
2. The State Minister for the Environment;;
3. The State Minister for Research and Technology/Chairman of the Agency for Assessment and Application of Technology;
4. Minister of Industry and Trade;
5. Minister of Education and Cultural;
6. Head of Inspection of Financial and Development Agency;
7. Head of Indonesian Science Institute;
8. Head of National Atomic Energy Agency;

Attachment List : Joint Decree of Minister Agriculture, Minister of Forestry and Estate Crops, Minister of Health, and State Minister of Food and Horticulture.

Number : 998.1/Kpts/OT.210/9/99
790.a/Kpts-IX/1999
1145A/MENKES/SKB/IX/199
015A/NmenegPHOR/09/1999

Date : 29 September 1999

ATTACHMENT LIST AND FORM OF BIOSAFETY AND FOOD SAFETY OF GENETICALLY ENGINEERED AGRICULTURAL PRODUCTS

| No. | Attachment Code/Model | Attachment/Form | Article |
|-----|-----------------------|--|-----------|
| 1 | I | Memberships, Duty, and Responsibility of Biosafety and Food Safety Committee | 39 para 1 |
| 2 | A | Application Letter for the Assessment of Biosafety and Food Safety of Genetically Engineered Agricultural Products | 37 para 1 |
| 3 | B | Evaluation on the Application of Assessment of Biosafety and Food Safety of Genetically Engineered Agricultural Products | 40 para 1 |
| 4 | C | Report of BFS TT on Assessment of Biosafety and Food Safety of Genetically Engineered Agricultural Products | 40 para 4 |
| 5 | D | Recommendation Letter of the Biosafety and Food Safety Committee concerning Safe or Not Safe of Genetically Engineered Agricultural Products | 41 para 1 |

MINISTER OF AGRICULTURE

MINISTER OF FORESTRY AND ESTATE CROPS

SOLEH SOLAHUDDIN

MUSLIMIN NASUTION

MINISTER OF HEALTH

STATE MINISTER OF FOOD AND HORTICULTURE

F. A. MOELOEK

A. M. SAEFUDDIN

ATTACHMENT I.

JOINT DECREE OF THE MINISTER OF AGRICULTURE, THE MINISTER OF FORESTRY AND ESTATE CROPS, THE MINISTER OF HEALTH, AND THE STATE MINISTER OF FOOD AND HORTICULTURE

NUMBER : 998.1/Kpts/OT.210/9/99
790.a/Kpts-IX/1999
1145A/MENKES/SKB/IX/199
015A/NmenegPHOR/09/1999

DATE : 29 September 1999

CONCERNING : BIOSAFETY AND FOOD SAFETY COMMITTEE
GENETICALLY ENGINEERED AGRICULTURAL
PRODUCTS

MEMBERSHIP, DUTY AND RESPONSIBILITY OF BIOSAFETY AND FOOD SAFETY COMMITTEE (BFSC)

A. MEMBERSHIP

The membership of BFSC as follows:

- I. Chairman I : Director General of Agency for Agricultural Research and Development, Department of Agriculture;
- Chairman II : Director General of Agency for Forestry and Estate Crops Research and Development, Department of Forestry and Estate Crops;
- Chairman III : Director General of Food and Drug Inspection, Department of Health;
- Chairman IV : Assistant of State Minister of Food and Horticulture Division on Quality and Food Safety;
- II. Secretary I : Director of Central Research Institute for Food Crops, the Agency for Agricultural Research and Development, Department of Agriculture;

- Secretary II : Director of Directorate of Food and Beverage Inspection, Directorate General of Food and Drug Inspection, Department of Health;
- Secretary III : Director of Central Research Institute for Estate Crops, Agency for Forestry and Estate Crops Research and Development, Department of Forestry and Estate Crops;
- III. Member : 1. Director of Research and Development Center for Biotechnology, Indonesian Science Institute (LIPI);
2. Manager of Center for Assessment and Application of Industrial and Agricultural Biotechnology, Agency for Assessment and Application of Technology;
3. Director of Center for Drug and Food Investigation, Directorate General of Food and Drug Inspection, Department of Health;
4. Director of Research and Development Center for Nutrition, Department of Health;
5. Director of Research and Development Center for Pharmaceutical, Department of Health;
6. Director of Animal Health, Directorate General of Animal Husbandry, Department of Agriculture;
7. Assistant to Deputy I Concerning Environment Conservation and Development, State Ministry of Environment;
8. Director of Central Research Institute for Animal Husbandry, the Agency for Agricultural Research and Development, Department of Agriculture;
9. Director of Central Research Institute for Horticulture Crops, the Agency for Agricultural Research and Development,

- Department of Agriculture;
10. Director of Central Research Institute for Fishery, the Agency for Agricultural Research and Development, Department of Agriculture;
 11. Director of Legal Bureau, Department of Agriculture;
 12. Director of Legal Bureau, Department of Health;
 13. Assistant to Deputy State Minister of Food and Horticulture, Division of Quality and Food Safety;
 14. Director of Inter University Center for Biotechnology, Bogor Agricultural Institute;
 15. Chairman of Indonesian Biotechnology Consortium;
 16. Chairman of Indonesian Society for Agricultural Biotechnology;
 17. Chairman of Indonesian Society for Breeding;
 18. Chairman of National Commission for Germplasms;
 19. Chairman of KEHATI Foundation;
 20. Chairman of Indonesian Consumer Foundation;
 21. Chairman of Indonesian Farmers Federation.

B. DUTY OF BFSC

Duty of BFSC as follows:

1. To develop policy and assessment procedure of biosafety and food safety, and monitoring of Genetically Engineered Agricultural Products (GEAP);
2. To issue some advice and technical consideration about biosafety and food safety for the utilization of GEAP;
3. To carry out the technical assessment on the application of biosafety and food safety for the utilization of GEAP;
4. To recommend about safe or not safe of GEAP as one of the consideration for the utilization of GEAP;

5. To give some advice in the management and control in the case of the utilization of GEAP causes biosafety and food safety harm;
6. To develop collaboration and consultation among various domestic institution and foreign country in biosafety and food safety of GEAP;
7. To prepare some relevant information about the implementation of biosafety and food safety for the utilization of GEAP;
8. To evaluate and assess biosafety and food safety due to the utilization of GEAP.

C. RESPONSIBILITY OF BFSC

Responsibility of BFSC as follows:

1. To evaluate a report on technical assessment results of biosafety and food safety of GEAP from the Biosafety and Food Safety Technical Team (BFSTT);
2. To safely keep the confidentiality and secrecy of the documents which relate to the technical and trade aspects in the assessment application of biosafety and food safety of GEAP;
3. To report the implementation of their duty and responsibility to the Minister of Agriculture, Minister of Forestry and Estate Crops, Minister of Health, and State Minister of Food and Horticulture in line with the authority of each Minister at least once a year.

D. OTHERS

1. In implementing their duty, BFSC is assisted by BFSTT, which their membership, duty, and responsibility is determined by Joint Decree of the Director General of the Agency for Agricultural Research and Development, Director General of the Agency for Forestry and Estate Crops Research and Development, Director General of Food and Drug Inspection, and Assistant of State Minister of Food and Horticulture Division on Quality and Food Safety.
2. All expenses required in the implementation of BFSTT's are born by the Department of Agriculture, Department of Forestry and Estate Crops, Department of Health, and the State Ministry of Food and Horticulture in line with the authority of each Minister.

MINISTER OF AGRICULTURE

MINISTER OF FORESTRY AND ESTATE CROPS

SOLEH SOLAHUDDIN

MUSLIMIN NASUTION

MINISTER OF HEALTH

STATE MINISTER OF FOOD AND HORTICULTURE

F. A. MOELOEK

A. M. SAEFUDDIN

**Application Letter for
the Assessment of Biosafety and Food Safety of
Genetically Engineered Agricultural Products**

Number :
Attachment :
Subject : Application for the Assessment of Biosafety and Food Safety of Genetically Engineered Agricultural Products To Related Director General

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 for the Assessment of Biosafety and Food Safety of Genetically Engineered Agricultural Products

As the material for your considerations enclosed are data and documents concerning the answers on the questions, 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 and Food Safety Committee
*) delete the inapplicable

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, Department of Forestry and Estate Crops, Department of Health, and State Ministry of Food And Horticulture 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 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 name of Genetically Engineered Agricultural Product is to be released? In case of being relevant, give some information concerning strain, cultivar, pollution and so on.
- A2 Would such Genetically Engineered Agricultural Product cause illnesses or disturbance to the health of human beings, plants or animals? If yes, what effects may occur?
- A3 (i) What did the exogenous genetic material come from? Give information 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 Product?
- (ii) What are the benefits of the chosen method in comparison to other methods?

Location

- A5 Clarify how many Genetically Engineered Agricultural 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?
- (i) Clarify in details the relevant nature of the physical environment, particularly those which may cause undesired consequences.
- (ii) How far is the location of the utilization from the residential area, center of agricultural activities, or the habitat of the Genetically Engineered Agricultural Products which may have an effect or be affected?

Habitat and ecology

- A7 (i)What is the natural habitat of the parent of said genetically engineered agricultural products, and what is the extent of its scope?
(ii)Where were the parents of such genetically engineered agricultural 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 products, strange in Indonesia?
- A8 Are there other organisms in Indonesia acting as predator or parasites against the genetically engineered agricultural products, which are to be released?
- A9 Would the utilization of genetically engineered agricultural products disrupt the function of the parent which is useful to the environment?
- A1 Clarify each ecological effect, directly or indirectly, that may be anticipated as a
0 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 products

- A1 What genetic traits have been engineered? Clarify in details about the steps that
1 have been taken.
- A1 Would the genetically engineered agricultural products genotypically have the
2 opportunity of becoming unstable?
- A1 (i)How far has the genetic modification been characterized? Give the data
3
- (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 products at the laboratory or in the field?
- A1 (i)What types of vectors are used to carry out the transformation? Clarify such
4 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 being found in the genetically engineered agricultural products? If not, how to remove such recombinant vector?

A1 In case no vector is used:

5

(i) if exogenous nucleic acid exists in the genetically engineered agricultural products, how were they inserted?

(ii) How many copies of the genes are inserted?

(iii) What genetically side effects are to be anticipated?

A1 How does the genetic modification change the phenotype of genetically engineered agricultural products, which will be released? Give the data to show the effect of modification, including the level of expression and regulation of the inserted gene

6

A1 (i) If any, which intrinsic genetic trait of the genetically engineered agricultural products could control its persistence and dispersion in nature? How stable are these traits?

7

(ii) What genetic changes, if any, have been done on the genetically engineered agricultural products to limit or to lose its ability to reproduce or to transfer its gene to other genetically engineered agricultural products?

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

A1 Based on contained experiment or other relevant experience, give the data pertaining to:

8

(i) the persistence of genetically engineered agricultural products in the planned habitat of utilization;

(ii) parental growth rate and the genetically engineered agricultural products in the secured environment and period of utilization

(iii) the frequency of reversion or losing the genetically modified traits

A1 (i) How is the spreading capability of the genetically engineered agricultural products from the place of utilization? How is the dispersal mechanism:

9

through the air, water or ground?

(ii) Can the parent create a structure to survive for a long period such as seeds or spores?

A2
0 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?

A2
1 Do the modified characteristics give the selective benefit to the genetically engineered agricultural products? If yes, under what condition? Give data concerning growth rate with or without the selection pressure

A2
2 Do you expect that the genetically engineered agricultural 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

A2
3 (i) Clarify in detail the protocol of utilization trial, the protocol of control, and testing of the genetically engineered agricultural products

(ii) How many genetically engineered agricultural products are planned to be released?

(iii) How many genetically engineered agricultural products are proposed to be released?

A2
4 (i) What plans have been made to multiply the genetically engineered agricultural products in a large number and its transfer to the place of the experiment?

(ii) How will the genetically engineered agricultural products be released?

A2 (iii) What method will be applied to test the inter batch variability in case the

- 5 genetically engineered agricultural products are needed in large quantity?
 (iv)What special precaution has been or will be taken in the production process to ensure the quality/purity achievement of the genetically engineered agricultural products?
- A2 (i)How to monitor the persistence of the genetically engineered agricultural
 6 products? Give a clarification concerning the technique of monitoring the presence and movement of the genetically engineered agricultural 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?
- A2 (i)If any, what potential hazard and harmful effect could be suspected and how
 7 could that possibility be evaluated during the utilization process?
 (ii)Explain each procedure applied to test the spreading of genetically engineered agricultural products.
 (iii)Should the gene transfer resulted in the adverse consequence (see question A20), what methods could be applied to minimize the consequences?
- A2 (i)Will the genetically engineered agricultural products remain exist in the
 8 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 products after they have been released? If yes, give the details.
 (iii)What monitoring could be done after the trial has been completed?
- A2 What measures could be taken to eliminate the genetically engineered
 9 agricultural products in case the danger arises during the utilization trial?
- A3 Explain all procedures of supervision and safeguarding to be done by the
 0 executors.
- A3 Explain the method of disposing of any used materials.
 1

Other evaluation methods

- A3
2 Has the BFSC ever evaluated an application to develop a small scale genetically engineered agricultural products? If yes, what are the results?
- A3
3 (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 evaluations?
(ii)Is there any country denied the application for the utilization of the genetically engineered agricultural products? If yes, what is the basis of such denial?
(iii)What factors would possibly cause a serious/less serious risk in the utilization proposed in Indonesia when compared to the utilization proposed abroad?
- A3
4 Are the genetically engineered agricultural products imported? If yes, give the documentation concerning the licensing or evaluation of the quarantine
- A3
5 Are there reasons to suspect that in case such genetically engineered agricultural 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 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 belonging 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 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 products in the area of intended release, give the details and quantify the chances of cross-pollination.
- (i) 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, do the mature seeds normally remain contained within an ear, capsule, pod etc. so that practically all of the seeds can readily be harvested, or do the seeds shed soon after they mature?
- (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 changed (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 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 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 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 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 evidence that the genetically engineered agricultural products are 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 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 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 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 products living in animals, will the genetically engineered agricultural 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 products in natural waters and soil?
 - (ii) What could be the effects of the genetically engineered agricultural products on water quality?
 - (iii) Do the genetically engineered agricultural products produce spores?
 - (iv) Are the genetically engineered agricultural products resistant to desiccation?

- C10 (i) What sterilizing and anti-microbial agents are active against the genetically engineered agricultural products?
- (ii) Are the genetically engineered agricultural 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 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 products on the partner plant species and how will this be monitored?
- (ii) What other secondary effects might the genetically engineered agricultural 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 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 products are 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 products in natural waters and soil?
- (ii) What are any possible/likely effects of the genetically engineered agricultural products on water quality?
 - (iii) Do the genetically engineered agricultural products produce spores?
 - (iv) Are the genetically engineered agricultural products resistant to desiccation?
- D7 What effects might the genetically engineered agricultural 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 products and closely related microorganisms in the partner plant (if applicable) or the environment of the site of introduction?
- D9 For genetically engineered agricultural products associated with plants, what effect they might have on insects, birds and animals (including humans) which may eat the plant?
- D10 Do the genetically engineered agricultural 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 products?
- (ii) Are the genetically engineered agricultural products susceptible to UV and ionizing radiation?

E. VERTEBRATES, NOT INCLUDING FISH

If transgenic animals 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.

- 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 Will the animals in this experiment be allowed to breed? If not, is breeding planned for later experiments or in the commercial phase?
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) above, 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 encoding 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 genetically engineered agricultural products are to be consumed as a food, answer also the questions in Section J.

F1 (i) Could the genetically engineered agricultural 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 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 genetically engineered agricultural products?

F2 (i) Will the genetically engineered agricultural 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 DNA 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 to other genetically engineered agricultural products? Specify the kinds of genetically engineered agricultural products and the problems.

F5 If natural populations of the genetically engineered agricultural products 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 genetically engineered agricultural products (e.g. cross-breeding of genetically engineered agricultural 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 genetically engineered agricultural product have any effect on the distribution and abundance of the genetically engineered agricultural products 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 products into other ecosystems?

G. INVERTEBRATES

If the genetically engineered agricultural product is to be consumed as a food, answer also the questions in Section J.

- G1 (i)What effects might the genetically engineered agricultural products have on the food chain?
(ii)Could the genetically engineered agricultural 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 products on the community ecology at the introduction site.
- G2 (i)Will the genetically engineered agricultural 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 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 gene of genetically engineered agricultural products have any effect on the structure 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 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 product have on the target species?
- H2 (i) What is the host range of the genetically engineered agricultural products? If the host range of the genetically engineered agricultural 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 products?
- (iii) What is the rationale for the choice of species tested?

- H3 Does the genetically engineered agricultural product 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 are the genetically engineered agricultural product 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 genetically engineered agricultural products.
- H7 Does the genetically engineered agricultural product produce metabolites which may have deleterious effects directly on other genetically engineered agricultural products or indirectly through concentration in the food chain? If so, elaborate.
- H8 Can the modified genetic traits be transmitted to other genetically engineered agricultural products which are likely to be in the environment (see A20), are these other genetically engineered agricultural products 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 products (e.g. increased resistance to the genetically engineered agricultural products)? 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 genetically engineered agricultural products have on the target substrate?
(iii) What effect does the genetically engineered agricultural product 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 products.

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

- J1 Is the parent organism or the DNA donor 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 product 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 metabolite products of the genetically engineered agricultural 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 product to be processed during the production of the food? If so, elaborate.

K. MICROORGANISMS AS LIVE VACCINES FOR VETERINARY USE

- K1 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.
- (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) pathogenicity and/or virulence.
- K2 What kind of genetically engineered agricultural products which have been inserted by recombinant vector? 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) 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 Assessment of Biosafety and Food Safety of Genetically Engineered Agricultural Products.

Filling Sheet

I. General 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 BFSTT. BFSTT has to send the application as well as filling sheet to BFSC 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 products

The sending of Genetically engineered agricultural products must fulfill the enclosed requirements.

Press Release

It is advisable that the applicant considers announcing 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, Department of Forestry and Estate Crops, Department of Health, and State Ministry of Food and Horticulture. See the Joint Decree on Biosafety and Food Safety of Genetically Engineered Agricultural Products for the requirements in detail.

2. Evaluation on the Application of Assessment of Biosafety and Food Safety of Genetically Engineered Agricultural Products

Filling Sheet

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

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

Committee's advice?

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| |

16 Will a press release on the work be distributed?

YES NO

→ If YES, when?

| |
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17 Provide details of any action taken to inform the public (local community etc.) about the assessment.

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| |

18 The information provided in the Assessment Proposal is, to the best of my knowledge, accurate:

| | |
|---------------------------------|----------------|
| Signature of Project Supervisor | |
| | Date / / |

19 The BFSTT has assessed and endorsed this proposal:

| | |
|------------------------------|-----------|
| Name of BFSTT Chairman | |
| Signature of BFSTT Chairman: | |
| | Date / |

20 CEO (or delegate) to countersign:

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Name of CEO
(or delegate)

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Signature of
CEO
(or delegate):

| |
|------------------|
| Date / / |
|------------------|

**Report of BFSTT on Assessment of Biosafety and Food Safety of
Genetically Engineered Agricultural Products**

Name of BFSTT:

No. of BFSC project review:

Title of Project:

Applicant:

Licenses received from the Competent Authority (date):

Location of Utilization:

Date of starting:

Date of ending:

Report summary

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 BFSC? Explain it.
- Is objective of the assessment 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 resist at the assessment place? 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 assessment?
- Is there any effect harming-damaging other agricultural products at the surrounding of place of assessment?

Signature of the Chairman of BFSTT

Date:

MODEL D

1. Recommendation Letter of the Biosafety and Food Safety Committee

Recommendation Letter of Safe or Not Safe on the Assessment of Biosafety and Food Safety of Genetically Engineered Agricultural Products

Number :
Attachment :
Subject : Recommendation on Safe/Not Safe on Assessment of
Biosafety and Food Safety of Genetically Engineered
Agricultural Products

To
Related
Directorate
General

Referring to your letter numberdated.....on the Application for the Assessment of Biosafety and Food Safety of Genetically Engineered Agricultural 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 and Food Safety Committee

Considering the Article 41 para. (1) of the Joint Decree of the Minister of Agriculture, the Minister Forestry and Estate Crops, the Minister of Health, and the State Minister of Food and Horticulture Number: 998.1/KPTS/OT.210/9/99; 790.A/KPTS-IX/1999; 1145A/MENKES/SKB/IX/199; 015A/NMENEGPHOR/09/1999 concerning Biosafety and Food Safety of Genetically Engineered Agricultural Products, we decide to recommend that the Genetically Engineered Agricultural Products which have been assessed is safe/not safe.

Please be informed and we thank you for your attention.

Biosafety and Food Safety Committee

2. Statement Letter of the Minister/Related Directorate General

Statement Letter of Safe or Not Safe on the Assessment of Biosafety and Food Safety of Genetically Engineered Agricultural Products

Number : _____ To _____
Attachment : _____
Subject : Recommendation on Safe/Not Safe on Assessment of
Biosafety and Food Safety of Genetically Engineered
Agricultural Products

Referring to your letter numberdated.....on the Application for the Assessment of Biosafety and Food Safety of Genetically Engineered Agricultural Products, and considering of recommendation letter from Biosafety and Food Safety Committee number.....dated....., I herewith forward the following:

1. The Genetically Engineered Agricultural Products, which was applied for assessment of biosafety and food safety through the application letter number... ..datedthat has been assessed based on the information and available data at the current time, we decide that the Genetically Engineered Agricultural Product is safe/not safe.
2. If there is some mistake in the future, so that this decision will be reevaluated.

Please be informed and we thank you for your attention.

Related Director General

Cc to:

1. Minister of Agriculture
2. Minister of Forestry and Estate Crops
3. Minister of Health
4. State Minister of Food and Horticulture
5. Biosafety and Food Safety Committee