

BIOLOGICAL SAFETY OF GENETIC ENGINEERING PRODUCTS
(Government Regulation No. 21/2005 dated May 19, 2005)

WITH THE GRACE OF THE ALMIGHTY GOD

THE PRESIDENT OF THE REPUBLIC OF INDONESIA,

Considering:

that, to enforce the provisions of Article 8 paragraph (2) clause b and paragraph (3) of Law No. 23/1997 (BN No. 6092 p. 19A-21A, etc.) on Environmental Treatment, it is necessary to stipulate Government Regulation on Biological Safety of Genetic Engineering Products.

In view of:

1. Article 5 paragraph (2) of Constitution of 1945 (BN No. 7152 p. 14A-23A);
2. Law No. 5/1984 on Ratification of United Nations Convention on Biological Diversity (Statute Book of 1994 No. 41, Supplement to Statute Book No. 3556);
3. Law No. 23/1997 (BN No. 6092 p. 19A-21A, etc.) on Environmental Treatment (Statute Book of 1997 No. 68, Supplement to Statute Book No. 3699);

D E C I D E S :

To stipulate
GOVERNMENT REGULATION ON BIOLOGICAL SAFETY OF GENETIC ENGINEERING PRODUCTS.

CHAPTER I
GENERAL PROVISIONS

Article 1

Hereinafter referred to as:

1. Biological safety of genetic engineering products is environmental safety, food safety and/or safety of food for the genetic engineering products.
2. Environmental safety is the condition and effort necessary to prevent potential risk that damages biological diversity as a result of utilization of genetic engineering products.

3. Safety of genetic engineering food products is the condition and effort necessary to prevent potential impact that damages and endangers human health as a result of production, preparation, storage, circulation, and utilization of genetic engineering products.

4. Food is anything not originating from biological sources and water, processed or unprocessed to food or drinks for human consumption, including food supplement, food raw material, and other materials used in process of preparation, processing, and/or making of food or drinks.

5. Safety of food for the genetic engineering products is the condition and effort necessary to prevent potential impact that damages and endangers animal and fish health as a result of process of production, preparation, storage, circulation, and utilization of genetic engineering

6. Food is raw material, supplementary material, and the extras or mixes thereof originating from biological sources, mineral, and water, processed or unprocessed and used as food for animals and/or fish.

7. Genetic engineering products or organisms as a result of modification, which is hereinafter called PRG, is living organisms, parts and/or results of processing thereof having new genetic structure as a result of application of modern biotechnology.

8. Modern biotechnology is application of genetic engineering technique consisting of in-vitro nucleic acid and cell fusion of two or more species of organisms beyond taxonomic genetic relation.

9. PRG animal is animal as a result of application of genetic engineering techniques which major or entire part of its live is on land.

10. PRG animal product is all products of PRG animal

- that can be further processed to human and other necessities.
11. Product of processing of PRG animal product is the product of PRG animal, which is processed with or without additional material.
 12. PRG fish is fish resources and other species of water biota, which major or entire part of their life cycle is in the water, as a result of application of genetic engineering techniques.
 13. PRG fish product is all materials produced from PRG fish and can be further processed to human and other necessities.
 14. Product of processing of PRG fish product is the product originating from PRG fish processed by certain ways or methods, with or without additional materials.
 15. PRG plant is a plant as a result of application of genetic engineering techniques.
 16. PRG plant product is the product of PRG plant that can be further processed to human and other necessities.
 17. Product of processing of PRG plant product is a product originating from PRG plant product, which is processed with or without additional materials.
 18. PRG microorganism is the microorganism produced by the application of genetic engineering techniques.
 19. PRG microorganism product is the body/cell of PRG microorganism and/or its metabolic product.
 20. Product of processing of PRG microorganism is a product originating from PRG microorganism's body/cell or its metabolic product processed by certain ways or methods with or without additional materials.
 21. PRG Risk Assessment is analysis into possible damaging impact on the environment, human health, and animal health as a result of development and utilization of PRG based on use of certain existing scientific methods and statistics.
 22. Assessment is the entire process of inspection into documents and PRG analysis and the related socio-economic factors.
 23. Analysis is technical evaluation and analysis on PRG consisting of techniques of engineering, efficacy, and requirements for biological safety at the laboratory, limited analysis facility and/or limited analysis field.
 24. Commission for Biological Safety of Genetic Engineering Products, which is hereinafter called KKH, is a commission having the duty to give recommendation to the Minister, authorized ministers, and head of non-departmental government institution (LPND) authorized to arrange and determine policies and to issue certificate of biological safety of PRG.
 25. Agency for Clearance of Biological Safety of Genetic Engineering Products, which is hereinafter called BKKH, is an instrument of KKH having the function as means of communication between KKH and stakeholders.
 26. Technical Team for Biological Safety of PRG, which is hereinafter called TTKH, is a team assigned to assist KKH in conducting technical evaluation and analysis into biological safety and worthiness of consumption of PRG.
 27. Announcement is the conveyance of information to public regarding result of technical evaluation and analysis into biological safety of PRG in the official gazette of KKH and announcement board or mass media before giving of recommendation regarding biological safety of PRG by KKH.
 28. Person is individual person, group of persons and/or corporations.
 29. Applicant is a person asking for license to the authorized Minister and/or head of LPND authorized to release and/or circulate PRG.

30. Release is a statement of recognition of breeding of high-yielding variety that can be distributed after meeting the requirements pursuant to the applicable laws.

31. Circulation is one or more activities in the framework of distribution of commodities to public, either for trade or not.

32. Authorized minister is the minister whose duties and functions are in the field of release and circulation of PRG.

33. Head of Non-Departmental Government Institutions, which is hereinafter called Head of LPND, is the Head of LPND whose duties and functions are in the field of circulation of PRG.

34. Day is calendar day.

35. Minister is the minister handling environmental affairs.

Article 2

(1) This Government Regulation is intended to create environmental safety, food safety, and/or safety of food for PRG and utilization of PRG in the fields of agriculture, fishery, forestry, industry, environmental, and non-pharmaceutical medicine.

(2) The purpose of this Government Regulation is to improve results and effectiveness of PRG for social welfare based on principles of health and treatment of biological resources, consumer protection, legal and business certainty.

Article 3

The clauses stipulated in this Government Regulation are based on precautionary approach in the framework of creating of environmental safety, food safety, and/or safety of food for PRG based on the existing scientific methods and in consideration of religious, ethical, socio-cultural, and aesthetic norms.

Article 4

This Government Regulation consists of clauses on:

- a. PRG types and the required conditions;
- b. PRG research and development;
- c. Introduction of PRG from foreign countries;
- d. Analysis, release and circulation, and use of PRG;
- e. PRG monitoring and control;
- f. Institutional affairs;
- g. Funding; and
- h. Sanctions.

CHAPTER II

PRG TYPES AND THE REQUIRED CONDITIONS

Part One

Types of PRG

Article 5

Types of PRG are:

- a. PRG animal, PRG animal products, and products of the processing thereof;
- b. PRG fish, PRG fish products, and products of the processing thereof;
- c. PRG plants, PRG plant products, and products of the processing thereof; and
- d. PRG microorganisms, PRG microorganism products, and products of the processing thereof.

Part Two

Required Conditions

Article 6

- (1) PRG, from domestic or foreign countries, analyzed or assessed before they are released and/or circulated in Indonesia, must be completed with basic information indicating that the products have met conditions of environmental safety, food safety, and/or safety of food for PRG.
- (2) The basic information indicating fulfillment of environmental safety, as set forth in paragraph (1), consists, amongst others:
 - a. Description and purpose of utilization;
 - b. Expected genetic and phenotypic changes must be detectable;
 - c. Clear identity on taxonomy, physiology, and reproduction of PRG;
 - d. Organisms used as sources of genes must be indicated clearly and comprehensively;

- e. The applied genetic engineering methods must follow the standard procedure that can be held accountable scientifically;
- f. Characteristics of PRG molecular must be described clearly;
- g. Expression of genes transformed to PRG must be stable;
- h. Destruction methods applied in case of deviation.

- (3) The basic information indicating fulfillment of requirements for food safety and safety of food for PRG, as set forth in paragraph (1), consist of, amongst others:
- a. The applied genetic engineering methods must follow the standard procedure that can be held accountable scientifically;
 - b. PRG's nutritional content must substantially be proportional to non-PRG;
 - c. Content of toxic, anti-nutrient compounds causing allergy in PRG must substantially be proportional to non-PRG;
 - d. Content of carbohydrate, protein, ash, fat, fiber, amino acid, fatty acid, mineral, and vitamin in PRG must substantially be proportional to non-PRG;
 - e. The protein contained in the gene must not cause allergy;
 - f. The destruction methods applied in case of deviation.

Article 7

Clauses regarding description of types of PRG, conditions for environmental safety, food safety, and/or safety of food for PRG will be further stipulated by the Minister, the authorized minister, or head of the authorized PLND according to their respective duties and functions.

CHAPTER III

PRG RESEARCH AND DEVELOPMENT

Article 8

Every person who carries out PRG research and development must prevent and/or solve the negative impact of its activities on human health and on the environment.

Article 9

PRG analysis during research and development

process must be conducted at the laboratory, limited analysis facility and/or limited analysis field.

Article 10

PRG generated by research and development, as set forth in Article 9, before they are proposed to be released and/or circulated, an efficacy test must be conducted and it must meet biological safety conditions.

Article 11

- (1) The government shall develop participation of all components of the society to conduct research and development to produce PRG, domestically.
- (2) In the framework of development of participation of the society, as set forth in paragraph (1), the government may give appreciation to people who produce new PRG useful for national interest.
- (3) In a society, which has not been able to participate in PRG research and development, the society shall conduct research and development to produce PRG.

Article 12

- (1) PRG research and development shall be conducted pursuant to laws on research, development, and application of science and technology.
- (2) Procedure of the implementation of PRG research and development, as set forth in paragraph (1), will be further stipulated by the authorized minister or Head of the authorized LPND.

CHAPTER IV

INTRODUCTION OF PRG FROM FOREIGN COUNTRIES

Article 13

- (1) Every person who will introduce similar PRG from foreign country for the first time must submit application to the authorized minister or to head of the authorized LPND.
- (2) The application for introduction of PRG must be completed with document certifying that the conditions of environmental safety, food safety, and/or safety of food for PRG as set forth in Article 6, have been met.

- (3) Other than meeting the provisions of paragraph (2), the introduction of PRG from foreign countries must also be completed by:
- a. Certificate of free trade of PRG in the country of origin; and
 - b. Documents of risk analysis and handling from the authorized institution where risk analysis has ever been conducted.
- (4) After receiving the application, as set forth in paragraph (1), the authorized minister or head of the authorized LPND shall:
- a. Inspect completeness of the documents and the requirements, as set forth in paragraphs (2) and (3);
 - b. Notify the applicant regarding completeness of the documents and the requirements that must be fulfilled by the applicant in accordance with the applicable laws on introduction of PRG not later than 15 (fifteen) days since receipt of the application.
- (5) In case that the documents and the requirements, as set forth in paragraphs (2) and (3), have been complete, the authorized minister or head of the authorized LPND shall ask for environmental safety recommendation from the Minister.
- (6) The authorized minister or head of the authorized LPND must base its decision on biological safety recommendation given by the Minister or Head of KKH.
- (7) Clauses regarding requirements and procedure of introduction of PRG from foreign countries will be further stipulated by the authorized minister or head of the authorized LPND.
- (2) The assessment shall be conducted based on the written proposal submitted by the applicant to the authorized minister or head of the authorized LPND.
- (3) After receiving the application, as set forth in paragraph (2), the authorized minister or head of the authorized LPND, within a period of not later than 14 (fourteen) days, shall submit recommendation of biological safety of PRG to the minister or Head of KKH.

Article 15

- (1) In the framework of giving of the recommendation of biological safety of PRG, as set forth in Article 14 paragraph (3), the Minister, the authorized minister, or head of the authorized LPND shall assign KKH to perform assessment.
- (2) The assessment, as set forth in paragraph (1), shall be performed not later than 14 (fourteen) days since receipt of letter of assignment.
- (3) In case that the assessment is related to technical evaluation, KKH shall assign TTKH to assess technical document and to carry out further analysis, if necessary.
- (4) The analysis of the technical document, as set forth in paragraph (3), shall be done not later than 56 (fifty-six) days since receipt of the letter of assignment from KKH.
- (5) Result of technical evaluation and analysis into biological safety of PRG conducted by TTKH shall be delivered to KKH as materials for arrangement of recommendation of biological safety of PRG within not later than 7 (seven) days after completion of the technical evaluation and analysis.

CHAPTER V ASSESSMENT, RELEASE AND CIRCULATION, AND UTILIZATION OF PRG

Part One Procedure of Assessment Article 14

- (1) Assessment of PRG must be conducted before it is released and circulated.

Article 16

- (1) On the result of technical evaluation and analysis submitted to KKH, as set forth in Article 15 paragraph (5), BKKH as an instrument of KKH, not later than 15 (fifteen) days shall announce the receipt of the application, process, and summary of result of analysis at a place accessible by the public for 60

(sixty) days to give opportunity to the society to give their response.

- (2) The conveyed information, as set forth in paragraph (1), does not include commercial information relating to intellectual property rights and not relating to biological safety.
- (3) If, within the time of the announcement, as set forth in paragraph (1), the society does not give any response, the society is deemed not objecting the recommendation of KKH.
- (4) After expiration of the time of announcement to public, as set forth in paragraph (1), BKHH shall submit report on public response to KKH within a period of not later than 7 (seven) days.
- (5) KKH shall submit recommendation of environmental safety to the Minister, recommendation of food safety and/or safety of food for PRG to the authorized minister or head of the authorized LPND within not later than 14 (fourteen) days since receipt of the report from BKKH.

Article 17

- (1) In submitting the recommendation of biological safety of PRG to the Minister, the authorized minister, or head of the authorized LPND, Head of KKH shall consider the recommendation of TTKH and input from the society.
- (2) In case that the PRG is a commodity that will be released to the environment, the Minister shall submit recommendation of environmental safety to the authorized minister or head of the authorized LPND within not later than 14 (fourteen) days since receipt of the recommendation from KKH.

Article 18

- (1) The written application, as set forth in Article 14 paragraph (2), must be completed by the documents as set forth in Article 6 paragraphs (2) and (3).
- (2) Inspection into the documents, as set forth in para-

graph (1), shall be conducted on:

- a. Administrative completeness;
- b. Substantive information;
- c. Additional information on the assessed species, consisting of:
 - i. Special purposes of evaluation and location, habitat, and ecology;
 - ii. Explanation regarding PRG genetic, trial procedure, monitoring, genetic data and stability; and
- d. Applicant's identity consisting of deed of establishment/legal documents and taxpayer's identification number (NPWP).

Article 19

- (1) The applicant must carry out environmental safety assessment at the laboratory, limited assessment facility and/or limited assessment field on PRG proposed to be released and/or circulated to the environment for the first time.
- (2) The applicant must perform food safety assessment at the laboratory on PRG proposed to be circulated for the first time.
- (3) The applicant must perform assessment of safety of food for PRG at the laboratory, limited assessment facility, and/or limited assessment field on PRG proposed to be circulated for the first time.

Article 20

- (1) The biological safety assessment, as set forth in Article 19, shall be conducted by a competent institution.
- (2) The institution, as set forth in paragraph (1), must have qualifications:
 - a. Having human resources competent to conduct assessments of environmental safety, food safety, and/or safety of food for PRG; and
 - b. Having access to accredited laboratory and limited assessment facility.
- (3) The laboratory and the limited assessment facility, as set forth in paragraph (2) clause b, must:

- a. have adequate facility and equipment;
- b. use methods of assessments of environmental safety, food safety, and/or safety of food for PRG; and
- c. guarantee honesty of the result of assessments.

(4) Guidelines for the biological safety assessment, as set forth in paragraph (3) clause b, will be further stipulated by the Minister, the authorized minister or head of the authorized LPND in accordance with their respective fields.

Article 21

(1) KKH shall assign BKKH to announce the summary of result of analysis of PRG conducted by TTKH to public through the mass media, printed or electronic, and the official gazette of KKH for 60 (sixty) days since receipt of the technical analysis from TTKH.

(2) During the time of the announcement, as set forth in paragraph (1), the public shall have an opportunity to give response in writing to KKH.

(3) Public response, as set forth in paragraph (2), delivered to KKH after the time, as set forth in paragraph (1), will not be considered.

(4) Based on the result of analysis of TTKH and inputs from the public, KKH shall submit recommendation regarding:

- a. whether PRG is safe or unsafe to the environment, to the Minister;
- b. whether PRG is safe for food and/or whether the food for PRG is safe or unsafe, to the authorized minister and/or head of the authorized LPND.

(5) PRG, which has been qualified in the analysis, will be given a certificate of qualification of environmental safety, food safety and/or safety of food for PRG by KKH and delivered to the Minister accompanied with the recommendation as set forth in paragraph (4).

(6) In case that PRG is not qualified in the analysis, KKH shall deliver to the Minister, the authorized minister

and/or head of the authorized LPND, its disapproval and the reasons of the disapproval.

Article 22

(1) Based on the recommendation of environmental safety, food safety and/or safety of food for PRG from KKH, as set forth in Article 21 paragraph (4):

- a. The Minister shall deliver recommendation of environmental safety to the authorized minister or head of the authorized LPND completed with a certificate of environmental safety;
- b. The authorized minister or head of the authorized LPND shall issue certificate of food safety and/or safety of food for PRG.

(2) The authorized minister or head of the authorized LPND shall consider the certificate and the recommendation, as set forth in paragraph (1), for issuance of License for Release and/or Circulation of PRG in accordance with the applicable laws.

Part Two

Release and Circulation of PRG

Article 23

On PRG that has obtained biological safety recommendation, as set forth in Article 16 paragraph (5) and Article 17 paragraph (2), the authorized minister or head of the authorized LPND shall give license for release and/or circulation in accordance with the laws in force.

Part Three

Utilization of PRG

Article 24

PRG, as set forth in Article 5, that has been released, as set forth in Article 23, may be used in various fields according to the purposes as written on the license.

CHAPTER VI

MONITORING AND CONTROL OF PRG

Article 25

The Minister, the authorized minister or head of the authorized LPND shall perform monitoring and control of PRG circulating and utilized in the Indonesian territory in accordance with the applicable laws.

Article 26

- (1) The Minister, the authorized minister, or head of the authorized LPND shall determine guidelines for monitoring of impact and risk management in consideration of input of KKH.
- (2) The monitoring, as set forth in paragraph (1), shall be performed by the minister, the authorized minister, or head of the authorized LPND in accordance with the applicable laws.

Article 27

- (1) Every person producing, introducing from foreign country and/or circulating PRG who knows about its negative impact on the environment, human health, and/or animal health, must report the event to the Minister, the authorized minister, and/or head of the authorized LPND.
- (2) Consumers and public knowing that PRG that has been released, circulated, and/or utilized, generates negative impact on the environment, human health, and/or animal health, may report the event to the Minister, the authorized minister, and/or head of the authorized LPND.
- (3) The Minister, the authorized minister, and/or head of the authorized LPND, after receiving the report, as set forth in paragraphs (1) and (2), shall assign KKH to inspect and to prove the verity of the report.
- (4) If, result of the inspection indicates that the reported PRG generates negative impact on the environment, human health, and/or animal health:
- a. The Minister shall propose the authorized minister or head of the authorized LPND to revoke the license for release or circulation of PRG;
 - b. The authorized minister or head of the authorized LPND shall revoke the license for release or circulation of PRG.

- (5) If the released, circulated, and/or utilized PRG generates negative impact on the environment, human health, and/or animal health, the party responsible for such activities must carry out control and preventive actions and shall withdraw PRG from circulation.

- (6) Further provisions on withdrawal of PRG will be stipulated by the authorized minister or head of the authorized LPND, based in input from KKH.
- (7) The procedure of the reporting, as set forth in paragraphs (1) and (2), shall be in accordance with the applicable laws.

CHAPTER VII
INSTITUTIONAL AFFAIRS

Part One

Commission for Biological Safety of PRG (KKH)

Article 28

KKH shall give biological safety recommendation to the Minister, the authorized minister, and head of the authorized LPND, as set forth in Article 22 paragraph (2) and shall assist the monitoring over introduction and utilization of PRG and inspection into the verity of the report on the existence of negative impact, as set forth in Articles 21, 26, and 27.

Article 29

- (1) The position, composition of members, duties, and functions, and authorities of KKH will be further stipulated in Presidential Regulation at the proposal of the Minister.
- (2) The Minister's proposal, as set forth in paragraph (1), shall be made in observance of the recommendation and consideration of the authorized minister and/or head of the authorized LPND.

Article 30

Before stipulating the enforcement regulations of this Government Regulation, the Minister, the authorized minister, or head of the authorized LPND, in accordance with their respective duties, must observe the recommendation and consideration of KKH.

Part Two

Agency for

Clearance of Biological Safety of PRG (BKKH)

Article 31

- (1) BKKH is an element of KKH in managing and presenting information to public.

(2)BKHH shall have duties:

- a. To manage and present information to public regarding procedure, receipt of application, process and summary of result of analysis;
- b. To receive input from public and to deliver result of analysis of such input;
- c. To inform the recommendation that will be delivered to the Minister, the authorized minister, or head of the authorized LPND; and
- d. To inform Decrees of the Minister, the authorized minister, or head of the authorized LPND regarding analyzed applications, to public.

Part Three

Technical Team for Biological Safety of PRG (TTKH)

Article 32

(1)TTKH shall have duty to assist KKH in carrying out technical analysis on biological safety.

(2)Further provisions regarding position, composition of members, duties and functions, and authorities of TTKH will be stipulated by the Chairperson of KKH in observance of the recommendation and consideration of the Minister, the authorized minister, and head of the authorized LPND.

(3)The members of TTKH, as set forth in paragraph (2), consist of experts of various sciences relating to PRG.

CHAPTER VIII

FUNDING

Article 33

All costs for the enforcement of this Government Regulation shall be decided in accordance with the applicable laws on state finances.

CHAPTER IX

TRANSITORY PROVISIONS

Article 34

All applications for release and/or circulation of PRG that have been submitted to the authorized minister or head of the authorized LPND and are being processed when this Government Regulation starts to be applicable, will be settled pursuant to the provisions of the existing laws.

Article 35

If the accredited laboratory or limited assessment facility, as set forth in Article 20 paragraph (1), does not exist, the Minister, the authorized minister, or head of the authorized LPND may appoint a laboratory or limited assessment facility that meets the minimum technical qualifications in accordance with this Government Regulation.

CHAPTER X

CLOSING PROVISIONS

Article 36

When this Government Regulation is applicable, all laws relating to environmental safety, food safety, and/or safety of food for PRG will still be applicable as long as they are not in contradiction with this Government Regulation.

Article 37

This Government Regulation starts to be applicable from the date it is promulgated.

For public cognizance this Government Regulation shall be promulgated by placing it in the Statute Book of the Republic of Indonesia.

Stipulated in Jakarta

On May 19, 2005

THE PRESIDENT OF THE REPUBLIC OF INDONESIA

Sgd

Dr. H. SUSILO BAMBANG YUDHOYONO

Promulgated in Jakarta

On May 19, 2005

THE MINISTER OF LEGAL AFFAIRS AND
HUMAN RIGHTS OF THE REPUBLIC OF INDONESIA

Sgd

HAMID AWALUDIN

STATUTE BOOK OF THE REPUBLIC OF INDONESIA OF
2005 NO. 44

ELUCIDATION (TO BE CONTINUED)

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BIOLOGICAL SAFETY OF GENETIC ENGINEERING PRODUCTS
(Government Regulation No. 21/2005 dated May 19, 2005)
[Continued from Business News No. 7259 - 7260 pages 21A - 29A]

**ELUCIDATION
OF
GOVERNMENT REGULATION
NO. 21/2005
ON
BIOLOGICAL SAFETY OF GENETIC ENGINEERING PRODUCTS**

I. GENERAL

Indonesia is one of the countries in the world that has very rich and highly valuable biological diversity (mega biodiversity). This biodiversity is the grace and blessing of the One and Only God to human beings, therefore it has to be managed sustainably in order to improve social welfare and not to damage human health and the environment.

The utilization of the biodiversity by application of modern biotechnology that produces genetic engineering products (PRG) has supported agricultural production, food security, and improvement of quality of human lives.

Modern biotechnology, which is applied in generating PRG, consists of in-vitro nucleic acid and cell fusion. Deoxyribose nucleic acid, which is hereinafter called DNA, is a molecule consisting of four kinds of bases and elements of phosphatic sugar that generates genetic information of an organism. The benefits of the application of this technology are, amongst others, to increase production, to increase immunity to pests and diseases, and to improve immunity to environmental stresses. Yet, however, the application of this technology may generate potential risk on the environment, biodiversity, and human health. Such potential risk has to be reduced by precautionary approach.

Potential risk in the application and development of PRG has been discussed since the negotiation of draft of international convention on biodiversity in 1990, which was then adopted by the Convention of Biological Diversity (CBD) in 1992. In 1994, the convention was ratified by Law No. 5/1994. The convention provides, amongst others, safety in application of modern biotechnology, namely in Article 8 paragraph g and Article 19 paragraph (1) obliging every member country of the convention to arrange, determine, and enforce laws on biodiversity, which also rules about food security and/or security of food for PRG.

This Government Regulation is necessary because the existing laws have not sufficiently provided anything about PRG as set forth in the convention. Thus, systematic and effective rulings are necessary. This Government Regulation is the governing law for creating of biological safety, food safety, and/or safety of for PRG for social welfare based on principles of health and treatment of biological resources, consumer protection, and business certainty in observance of religion, ethics, social, cultural, and aesthetics.

This Government Regulation stipulates types and conditions of PRG, PRG research and development, introduction of PRG from foreign countries, assessment, release and circulation, and utilization of PRG, PRG control, institutional affairs and funding.

This Government Regulation, other than the further enforcement of the provisions of Article 8 paragraph (2) clause b and paragraph (3) of Law No. 23/1997 on Environmental Treatment, is also related to various laws. The related laws that support this Government Regulation include, amongst others:

- a. Law No. 6/1967 on Animal Husbandry and Animal Health (Statute Book of 1967 No. 10, Supplement to Statute Book No. 2824);
- b. Law No. 5/1984 on Industrial Affairs (Statute Book of 1984 No. 22, Supplement to Statute Book No. 3274);
- c. Law No. 5/1990 on Conservation of Biological Resources and The Ecosystem (Statute Book of 1990 No. 49, Supplement to Statute Book No. 3419);
- d. Law No. 12/1992 on Plant Cultivation System (Statute Book of 1992 No. 46, Supplement to Statute Book No. 3478);
- e. Law No. 16/1992 on Animal, Fish, and Plant Quarantine (Statute Book of 1992 No. 56, Supplement to Statute Book No. 3482);
- f. Law No. 23/1992 on Health (Statute Book of 1992 No. 100, Supplement to Statute Book No. 3495);
- g. Law No. 5/1994 on Ratification of the United Nations Convention on Biological Diversity (Statute Book of 1994 No. 41, Supplement to Statute Book No. 3556);
- h. Law No. 7/1994 on Ratification of the Agreement Establishing the World Trade Organization (Statute Book of 1994 No. 57, Supplement to Statute Book No. 3564);
- i. Law No. 7/1996 on Food (Statute Book of 1996 No. 99, Supplement to Statute Book No. 3656);
- j. Law No. 8/1999 on Consumer Protection (Statute Book of 1999 No. 42, Supplement to Statute Book No. 3821);
- k. Law No. 41/1999 on Forestry (Statute Book of 1999 No. 167, Supplement to Statute Book No. 3888) as already amended by Law No. 19/2004 on Ratification of Government Regulation In Lieu of Law No. 1/2004 on Amendment to Law No. 41/1999 on Forestry to into a Law (Statute Book of 2004 No. 86, Supplement to Statute Book No. 4412);
- l. Law No. 29/2000 on Protection of Plant Varieties (Statute Book of 2000 No. 241, Supplement to Statute Book No. 4043);
- m. Law No. 18/2002 on National System of Research, Development, and Application of Science and Technology (Statute Book of 2002 No. 84, Supplement to Statute Book No. 4219);
- n. Law No. 18/2004 on Plantation (Statute Book of 2004 No. 85, Supplement to Statute Book No. 4411);
- o. Law No. 21/2004 on Ratification of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Statute Book of 2004 No. 88, Supplement to Statute Book No. 4414);
- p. Law No. 31/2004 on Fishery (Statute Book of 2004 No. 118, Supplement to Statute Book No. 4433);
- q. Law No. 32/2004 on Regional Administration (Statute Book of 2004 No. 125, Supplement to Statute Book No. 4437).

This Government Regulation is the further stipulation on the use and release of living modified organisms and effective participation in biotechnological research relating to genetic engineering products.

II. ARTICLE BY ARTICLE

Articles 1 and 2

Sufficiently clear.

Article 3

Precautionary approach is an approach in decision-making to prevent potential impact on the environment and human health, even before conclusive scientific evidences regarding such impact have existed. In this Government Regulation, precautionary approach is set forth in the clause providing that before PRG is utilized, prior assessment and management of risk on environmental safety, food safety, and/or safety of food for PRG must necessarily be conducted by the existing scientific methods in consideration of social, economic, and aesthetic factors to ensure that the risk of the utilization of PRG on the environment and human health is acceptable based on the existing regulations. Considered from the religious, ethic, and socio-cultural factors, amongst others, the gene transformed to PRG must be derived from an organism, which is not in contradiction to certain religious norms; the form and phenotype of PRG animal must be in proportional to its parent and in accordance with the existing aesthetic norms.

Article 4

Sufficiently clear.

Article 5

Paragraph a

PRG animal, PRG animal products, and products of the processing thereof do not include wild animals.

Paragraph b

PRG fish, PRG fish products, and products of the processing thereof do not include protected fish and those included in CITES' Appendices.

Paragraph c

PRG plants, PRG plant products, and products of the processing thereof do not include wild plants.

Paragraph d

Sufficiently clear.

Article 6

Paragraph (1)

Sufficiently clear.

Paragraph (2)

Clauses a - c

Sufficiently clear.

Clause d

"Sources of genes must be indicated clearly and comprehensively" means that the origin, the status of

protection (protected/unprotected) of an organism used as source of gene must be clear, whether it is included in the CITES' Appendices I, II, and III or not. The certificate of origin must be complete.

Clause e

Sufficiently clear.

Clause f

"Clearly" means an evaluation in accordance with guidelines for analysis into molecular characteristics.

Clauses g and h

Sufficiently clear.

Paragraph (3)

Clause a

Sufficiently clear.

Clause b

"Substantially proportional" is a condition where transgenic product is substantially proportional to the original non-transgenic product, except on the engineered characteristics.

Clause c

"Content of toxic compound" means the existing content of compound in plant naturally, such as trypsin inhibitor, lectin, urease in soybeans, and non-toxic in soil bacteria, *Bacillus thuringiensis*, potential in causing death on certain insects.

Clauses d - f

Sufficiently clear.

Article 7

"Stipulated clauses" includes, amongst others, clauses on the purpose of utilization of PRG.

Articles 8 and 9

Sufficiently clear.

Article 10

Efficacy test is intended to assure that the interest gene has properly been transformed to an expressed PRG.

Articles 11 and 12

Sufficiently clear.

Article 13

Paragraph (1)

"Similar PRG" means similar PRG as a result of genetic engineering, including the breed of conventional

hybridizing. Similar varieties of different PRG are not similar PRG. The word "similar" is not in taxonomic terms.

A biological safety assessment must be carried out on similar PRG only for the first introduction. Once it has met the qualifications of biological safety, the following introduction of PRG of similar species is not necessarily subject to biological safety assessment. License from the Minister is only required for the first introduction of a PRG.

The application, pursuant to this paragraph, is only a notification by the person who will introduce PRG, to the Minister or head of the authorized LPND for biological safety assessment in the framework of acquiring of certificate of biological safety as one of the conditions for release and circulation of PRG.

Paragraphs (2) and (3)
Sufficiently clear.

Paragraph (4)
Besides the certificate stating that the PRG has been traded freely in the country of origin and document of assessment and management of risk, introduction of PRG from foreign countries must also in compliance with other applicable laws.

Paragraph (5)
Sufficiently clear.

Paragraph (6)
The authorized minister or head of the authorized LPND is, amongst others:

- Release of plant varieties is handled by the Minister of Agriculture;
- Release of fish is handled by the Minister of Marine and Fishery;
- Release of forestry plants is handled by the Minister of Forestry;
- Release of processed food is handled by Head of the Drug and Food Supervisory Agency.

Paragraph (7)
Clauses regarding requirements and procedure of introduction of PRG from foreign countries stipulated by the minister include, amongst others, fulfillment of laws on quarantine affairs.

Article 14
Paragraph (1)
Sufficiently clear.

Paragraph (2)
The authorized minister or head of the authorized LPND is, amongst others:

- Release of plant varieties is handled by the Minister of Agriculture;
- Release of fish is handled by the Minister of Marine and Fishery;
- Release of forestry plants is handled by the Minister of Forestry;
- Release of processed food is handled by Head of the Drug and Food Supervisory Agency.

Paragraph (3)
Sufficiently clear.

Article 15
Paragraphs (1) and (2)
Sufficiently clear.

Paragraph (3)
The time for further assessment at the laboratory, limited assessment facility (glass house, animal pen, pond, and coastal pond) and/or limited assessment field is based on the types and characteristics of the analyzed PRG.

Paragraphs (4) and (5)
Sufficiently clear.

Article 16
Sufficiently clear.

Articles 17 and 18
Sufficiently clear.

Article 19
Paragraph (1)
Assessment at the laboratory, limited assessment facility, and/or limited assessment field shall be done if information in the documents submitted by applicant has not assured KKH to make a conclusion for the giving of recommendation of environmental safety, food safety, and/or safety of food for PRG.

Paragraphs (2) and (3)
Sufficiently clear.

Article 20

Paragraph (1)

"Competent institution" includes, amongst others, university, research institution having adequate facility and capability.

Paragraph (2)

Sufficiently clear.

Paragraph (3)

"Limited assessment facility" means a facility that has met the minimum requirements for carrying out of biological safety assessment.

Paragraph (4)

Sufficiently clear.

Article 21

Paragraph (1)

Announcement to public is intended so that the society at large knows about the application for release and circulation of PRG. By such announcement, the society may have an opportunity to submit response in writing to KKH. Announcement is done, either by placing it in a publishing media provided by KKH or through BKKH, which is accessible by the society.

Paragraphs (2) - (4)

Sufficiently clear.

Paragraph (5)

Since the time of analysis, submission of response and input from the society stops, KKH must deliver materials for recommendation of biological safety to the Minister.

Paragraph (6)

Sufficiently clear.

Article 22

Sufficiently clear.

Article 23

Clauses on the release and/or circulation of PRG shall comply with the laws on the respective commodity. On PRG plants, the governing laws is Law No. 12/1992

on Plant Cultivation System, and on PRG fish, the governing law is Law No. 31/2004 on Fishery.

Article 24

Sufficiently clear.

Article 25

Monitoring and control by the authorized minister or head of the authorized LPND include, amongst others, decisions regarding the officer and/or institution that performs monitoring and procedure of monitoring of reports in accordance with the applicable laws on the respective commodity.

Article 26

Sufficiently clear.

Article 27

Paragraphs (1) - (4)

Sufficiently clear.

Paragraph (5)

"The party responsible for such activities" is every person who produces, introduces, and/or circulates PRG.

Paragraphs (6) and (7)

Sufficiently clear.

Articles 28 - 31

Sufficiently clear.

Article 32

Paragraphs (1) and (2)

Sufficiently clear.

Paragraph (3)

Members of TTKH consist of experts, because TTKH handles scientific analysis that can only be handled by experts in the respective fields.

Articles 33 - 37

Sufficiently clear.

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