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AUTHORIZED TRANSLATION  
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**DRAFT**

**GOVERNMENT REGULATION OF THE REPUBLIC OF INDONESIA**

**NUMBER ..... OF 2001**

**REGARDING**

**SAFETY OF LIVING ORGANISMS AND FOODS OF BIOTECHNOLOGICAL  
PRODUCTS (PBHRG) PRODUCED THROUGH GENETIC ENGINEERING**

**PRESIDENT OF THE REPUBLIC OF INDONESIA**

Considering : a. that Indonesia is a country with great diversity and high valuable (*mega biodiversity*) of living organisms which should be utilized optimally to improve people's welfare and cause no harm to people's health and environment.

b. that rapid development in science and technology has improved activities of research, development, release and circulation, import and utilization of biotechnological products produced through genetic engineering among others in the field of agriculture, food, forestry, industry and health;

c. that genetic engineering technology has a great potency for human life and if developed and utilized with adequate safety effort for environment and people's health.

- d. that *United Nations Convention on Biological Diversity* has been ratified by virtue of Law Number 5 of 1994;
- e. that based on the above matters and as implementation of Article 8 point (g) and Article 19 paragraph (1) of *United Nations Convention on Biological Diversity*, it is deemed necessary to establish Government Regulation on Safety of Living Organisms and Foods of Biotechnological Products produced through Genetic Engineering;

In a view of :

- 1. Article 5 paragraph (2) of 1945 Constitution;
- 2. Law Number 6 of 1967 on Provisions of Animal Husbandry and Health (State Gazette of 1967 Number 10, Supplement to the State Gazette Number 2824);
- 3. Law Number 9 of 1985 regarding Fishery (State Gazette of 1985 Number 46; Supplement to the State Gazette Number 3299);
- 4. Law Number 5 of 1990 regarding Conservation of Natural Resources and its Ecosystem (State Gazette Number 1990 number 49; Supplement to State Gazette Number 3419);
- 5. Law Number 12 of 1992 regarding Plant Cultivation System (State Gazette of 1992 Number 46; Supplement Number 3478);

6. Law Number 16 of 1992 regarding Animal, Fish and Plant Quarantine (State Gazette Number 56; Supplement to the State Gazette Number 3482);
7. Law Number 23 of 1992 regarding Health (State Gazette of 1992 Number 100; Supplement to State Gazette Number 3495);
8. Law Number 5 of 1994 regarding *Ratification of United Nations Convention on Biological Diversity* (State Gazette of 1994 Number 41, Supplement to the State Gazette Number 3556);
9. Law Number 7 of 1996 regarding Foods (Supplement to the State Gazette of 1996 Number 99; Supplement to the State Gazette Number 3656);
10. Law Number 23 of 1997 regarding Management of Living Environment (State Gazette of 1997 Number 68, Supplement to the State Gazette Number 3699;

**HAS DECIDED:**

To Stipulate: GOVERNMENT REGULATION OF THE REPUBLIC OF INDONESIA REGARDING SAFETY OF LIVING ORGANISMS AND FOODS OF BIOTECHNOLOGICAL PRODUCTS PRODUCED THROUGH GENETIC ENGINEERING.

**CHAPTER I**  
**GENERAL PROVISIONS**

**Article 1**

In this Government Regulation what we mean by:

1. Biotechnological products produced through genetic engineering hereinafter in short PBHRG shall be transgene animals, materials from transgene animals and their processed products; transgene fish, materials from transgene fish and their processed products; and transgene living remains, materials from transgene microorganism and their processed products.
2. Safety of Living Organisms shall be any condition and effort required to prevent possible emergence of something that may disturb, harm and endanger biological diversity comprising animal, fish, plant and microorganism, as well as living environment as a result of PBHRG utilization.
3. Food safety shall be any condition and effort required to prevent possible emergence of something which may disturb, harm and endanger people's health resulted from production, storage, circulation and preparation of PBHRG.
4. Feed safety shall be any condition and effort required to prevent possible emergence of something which may disturb, harm and endanger animals' health resulted from production, storage, circulation and preparation of PBHRG.

5. Genetic engineering technology shall be all efforts taken to make intentional modification to gene of living organism by adding, reducing and or modifying composition of original gene applying recombinant DNA technique.
6. Gene shall be total genetic complement of an organism.
7. *Deoxyribose Nucleic Acid* hereinafter referred to as DNA shall be molecule consisting of four types of acid and phosphate sugar frame taking genetic information of most organisms.
8. DNA recombinant shall be a DNA composition formed in a vitro manner from DNA fragments of two or more organisms.
9. Transgene animals shall be animals produced from genetic engineering which their most or entire lifetime is on land raised by human beings.
10. Materials from transgene animals shall be all materials produced from transgene animals and can be processed further for people's need and other needs.
11. Processed product material from transgene animal shall be any product made of transgene animal processed by certain method with or without additives.
12. Transgene fish shall be fish from class of Mammal, Reptile, Amphibian, Pisces, Crustacean, Mollusk, Coelenterate, Echinodermate, Algae, and other water species produced through genetic engineering.

13. Materials from transgenetic fish shall be all materials produced from transgenetic fish and can be processed further for human need and other needs.
14. Processed products of transgenetic fish shall be products made of transgenetic fish processed by certain technique or method with or without additives.
15. Transgene plants shall be all plants comprising seasonal plants and annual plants produced from genetic engineering.
16. Materials from transgenetic plant shall be all materials produced from transgene plants and can be processed further for human need and other needs.
17. Processed products of transgene plant shall be all products made of transgene plants processed by certain technique or method with or without additives.
18. Transgenetic microorganisms (comprising virus, bacteria, protozoa, mushroom, and micro algae) shall be microorganisms produced through transgene engineering.
19. Materials from transgene microorganism shall be (1) body/cell from transgene microorganism itself and its metabolism product.
20. Original material of transgene microorganism shall be (1) body/cell of the transgene microorganism itself and (2) its metabolism products.
21. Processed products of transgene microorganism shall be all products made of body/cell of transgene microorganism and

its metabolism product, processed with certain technique or method.

22. Substantial equivalent shall be a condition where transgene process substantially equals to non-transgene original product except its engineered character.
23. "Generally regarded as safe (GRAS)" shall be a safe condition for consumption applied to microorganism, *food additives* and *feed additive* and foods and feeds made of PBHRG.
24. The Minister shall be the Minister/Leader of Non-Departmental Government Agency in charge of PBHRG management.
25. National Commission for Safety of Living Organisms and Foods hereinafter referred to as KNKHKP shall be a team assigned to assist the Minister in formulating and establishing policies on the safety of living organisms and/or safety of Foods and or Feeds as well as feasibility of PBHRG utilization.
26. Technical Team for Safety of Living Organisms and Foods hereinafter referred to as TTKHKP shall be a team assigned to assist KNKHKP in conducting evaluation of and technical investigation on the safety of living organisms and/or safety of Foods and or Feeds as well as feasibility of PBHRG utilization.
27. Public announcement shall be effort to convey information on the result of evaluation of and technical investigation on KHKPKP on PBHRG before giving recommendations to **KHKPKP** to KNKHKP.

## **Article 2**

- (1) This Government Regulation is made to serve made as legal ground in the effort to realize the safety of living organisms, foods and feeds of PBHRG as well as their utilization in the field of agriculture, fishery, forestry, industry, health and environment.
- (2) This Government Regulation is intended to improve the benefit of PBHRG for people's welfare based on principles of health and living organism management, consumer protection and business operation certainty.

## **Article 3**

Regulative principle applied in this Government Regulation shall be prudential approach with the purpose of achieving the safety of living organisms, foods, and or feeds by taking into account religious, ethical, social-cultural and aesthetic aspects.

## **Article 4**

The scope of this Government Regulation covers:

- a. type and requirement of PBHRG;
- b. research and development of PBHRG;
- c. import of PBHRG;
- d. investigation, release, circulation and utilization of PBHRG;
- e. PBHRG control;
- f. Institutionalization; and
- g. Penalty provision.



**CHAPTER**  
**TYPE AND REQUIREMENT OF PBHRG**

**Part One**  
**Type of PBHRG**

**Article 5**

(1) Types of PBHRG shall cover:

- a. transgene animals, materials from transgene animals and their processed products;
- b. transgene fish, materials from transgene fish, and their processed products;
- c. transgene plants, materials from transgenic plants, and their processed products.
- d. transgene microorganisms, materials from transgene materials and their processed products.

(2) Further provision regarding detailed types of PBHRG shall be provided by the Minister.

**Part Two**  
**Requirements of PBHRG**

**Article 6**

PBHRG which comes from domestic or abroad shall be furnished with basic information indicating its compliance with the requirements for the safety of living organisms and or food and or woof security.

## **Article 7**

- (1) Basic information indicating its compliance with the requirements as referred to in Article 6 shall cover among others:
- a. clear identity on taxonomy, physiology, and reproduction of PBHRG;
  - b. organism used as gene source shall be stated clearly and completely;
  - c. genetic engineering method in use shall follow standard procedure the validity of which can be accounted for;
  - d. molecular characterization of PBHRG must be clear;
  - e. gene expression transformed to PBHRG must be stable;
  - f. expected change of genetic and phenotype must be detectable;
  - g. method of disposal in case of deviation.
- (2) Further provision on requirements as referred to in paragraph (1) shall be provided by the Minister.

## **Article 8**

- (1) Basic information as indication of compliance with safety requirements of foods and or feed as referred to in Article 6 shall cover among others:
- a. genetic engineering method in use shall follow standard procedure the validity of which can be accounted for;
  - b. Nutrition content of PBHRG must be substantially equivalent to non-transgene one;

- c. Toxic compound content, anti nutrition and allergy stimulator must be equivalent to non-transgene ones;
- d. Carbohydrate, protein, ashes, fat, fiber, amino acid, fat acid, mineral and vitamin content in PBHRG must be substantially equivalent to non-trangenetic ones;
- e. Protein transferred must not be allergen;
- f. Method of annihilation in use in case of deviation.

(2) Further provision on requirements as referred to in paragraph (1) shall be set forth by the Minister.

### **CHAPTER III**

#### **RESEARCH AND DEVELOPMENT OF PBHRG**

#### **Article 9**

Any person or corporate body which conducts research and development of PBHRG shall prevent and overcome negative impacts which may harm human health and environment.

#### **Article 10**

- (1) The Government motivates participation of all components of the community to conduct research and development to produce domestic PBHRG.
- (2) PBHRG produced from the research and development as referred to in paragraph (1) shall meet safety requirements for living organisms and or feeds of PBHRG as referred to in Articles 3, 7, and 8.

- (3) To push community participation as referred to in paragraph (1), the Government may grant reward to any community member who is able to produce new PBHRG giving benefits to national interest.
- (4) In the event that the community can not participate in the research and development of PBHRG, the Government shall conduct research and development to produce PBHRG.

#### **Article 11**

For the process of research and development, produced PBHRG shall be tested for efficacy, safety of living organism, and or food and feed at laboratory, limited testing facility and limited testing field.

#### **Article 12**

- (1) Foreign research institution intending to conduct research and development of PBHRG in Indonesia shall obtain permit from the Government and cooperate with qualified national institution research.
- (2) Requirements for national research institution as referred to in paragraph (1) shall have among others:
  - a. human resources that are able to conduct research and development;
  - b. adequate facilities and instruments; and
  - c. valid and safe testing method;

### **Article 13**

Requirements for institution and activities of research and development of PBHRG as referred to in Articles 9, 10, 11, and 12 shall be provided further by the Minister.

## **CHAPTER IV IMPORT OF PBHRG**

### **Article 14**

- (1) Any person or corporate body intending to import PBHRG shall file application and obtain approval from the Minister.
- (2) Application for import of PBHRG shall be furnished with documents substantially indicating compliance with safety requirements for living organism and or foods and or feeds as referred to in Articles 6, 7, and 8.
- (3) Other than requirements as referred to in Articles 6, 7, and 8, import of PBHRG shall be furnished with:
  - a. Certificate declaring that the PBHRG has been freely traded in the country of origin (*certificate of free trade*);
  - b. documentation of risk assessment and management from the relevant authorities where the risk assessment is conducted.
- (4) Requirements and procedure for import of PBHRG shall be provided further by the Minister.

**CHAPTER V**  
**INVESTIGATION, RELEASE, CIRCULATION AND UTILIZATION OF PBHRG**

**Point One**  
**Investigation**

**Article 15**

- (1) Any person or corporate body that will release and circulate PBHRG in Indonesia shall file a written application to the Minister.
- (2) After receiving the application as referred to in paragraph (1), the Minister shall conduct assessment on the safety of living organism, food and or feed of PBHRG before taking decision on the application.
- (3) PBHRG investigation is an activity to examine documents and examinations comprising test in laboratory, limited testing facility and limited testing field.

**Article 16**

- (1) Inspection of the documents as referred to in Article 15 paragraph (3) shall be made on substantive information as referred to in Articles 6, Articles 7 and Articles 8.
- (2) Information as referred to in paragraph (1) shall be furnished with additional information on species to be tested, specific purpose of testing, location, habitat, and ecology, PBHRG genetic, experimental procedure, monitoring, gene stability data.

- (3) In addition to the inspection document inspection as referred to in paragraphs (1) and (2), document completeness of applicant comprising deed of incorporation and taxpayer reference number shall also be inspected.

#### **Article 17**

If necessary, PBHRG applied for release, circulation, and utilization shall be tested for safety of living organism, food and or feed at laboratory, limited testing facility, and limited testing field.

#### **Article 18**

- (1) Safety testing of living organism and or food and or feed shall be made at laboratory and limited testing facility accredited or appointed by the Minister.
- (2) The laboratory and limited testing facility appointed by the Minister as referred to in paragraph (1) shall meet requirements of having:
- a. human resource able to conduct testing;
  - b. adequate facilities and instruments, and;
  - c. valid and safe testing method.
- (3) Further provision on the requirements of laboratory and limited testing facility as referred to in paragraph (1) shall be laid down by the Minister.

## **Article 19**

Laboratory and testing facility as referred to in Article 18 paragraph (1) shall guarantee correct testing findings and shall protect confidentiality of information received or produced.

## **Article 20**

- (1) Public announcement shall be made by KNKHKP three months before KNKHKP issues recommendation on the safety of living organism and or food and or feed.
- (2) During the term of announcement as referred to in paragraph (1), community members shall be given opportunity to give written responses to KNKHKP.
- (3) In the event that during the term of announcement as referred to in paragraph (1) there are responses from community members, KNKHKP shall perform assessment by involving the parties giving such responses as material of consideration for recommendation to the Minister.
- (4) The assessment as referred to in paragraph (3) shall be completed within no later than one month.
- (5) The responses from community as referred to in paragraph (2) given to KNKHKP after a lapse of the term as referred to in paragraph (1) shall not be accepted.

## **Article 21**

Procedure and term of assessment on the safety of living organism and or food and or feed of PBHRG shall be regulated further by the Minister.



**Par two**  
**Release and Circulation of PBHRG**

**Article 22**

- (1) PBHRG passing the assessment as referred to in the Part One shall be given certificate of safety of living organism and or food and or feed by The Minister.
- (2) PBGHR not passing the assessment as referred to in the Part One shall be given rejection letter by The Minister together with reason therefor.

**Article 23**

- (1) Applicant who has obtained certificate as referred to in Article 22 paragraph (1) can request decision for release from The Minister pursuant to the prevailing legislation.
- (2) Circulation of released PBHRG shall be in accordance with the purpose of release.

**Point Three**  
**PBHRG Utilization**

**Article 24**

- (1) PBHRG as referred to in Article 5 paragraph (1) and has been released as referred to in Article 23 paragraph (1) can be utilized to meet the need for foods and or feed, health, agriculture, fishery, forestry, industry, and environment.

- (2) PBHRG as referred to in Article 5 paragraph (1) and has been released as referred to in Article 23 paragraph (1) can be utilized as producer of food material, feed material, and or raw material of industry, and control of pests.
- (3) Transgene animal as referred to in Article 5 paragraph (1) points a and b, and has been released as referred to in Article 23 paragraph (1) can be utilized as hobby, sport, science and technology facility.
- (4) Transgene plant and fish transgenic as referred to in Article 5 paragraph (1) points c, and d, and has been released as referred to in Article 23 paragraph (1) can be utilized as decoration or decorative fish.
- (5) Transgene fish or microorganism as referred to in Article 5 paragraph (1) points c and d, and has been released as referred to in Article 23 paragraph (1) can be utilized for organic fertilizer and bio-remedy.
- (6) Transgene animal or plant as referred to in Article 5 paragraph (1) points a, and c, and has been released as referred to in Article 23 paragraph (1) can be utilized as medicine materials.
- (7) Transgene microorganism as referred to in Article 5 paragraph (1) point d, and has been released as referred to in Article 23 paragraph (1) can be utilized for pesticide, organic herbicide, probiotic, testing material of serology and animal biology activity, for production of

antigen, antisera, vaccine, and production process of bioactive organic compounds and main organic compounds.

## **CHAPTER VI**

### **CONTROL**

#### **Article 25**

PBHRG circulated for utilization within the Republic of Indonesia shall be controlled by the Minister.

#### **Article 26**

Any person or compare body obtaining decision for release and circulation of PBHRG shall periodically report on the circulation and utilization of PBHRG to the Minister at least once in a year.

#### **Article 27**

- (1) Producer, importer, and distributor identifying the adverse effect of the released, circulated, and or utilized PBHRG on human on health or environment can report the same to the Minister.
- (2) Consumer identifying adverse effect of PBHRG, the released, circulated and or utilized PBHRG on human health and or environment can report the same to the Minister.
- (3) After receiving report as referred to in paragraph (1) and paragraph (2), the Minister shall examine and verify for the correctness of the report.

- (4) If the result of examination proves that PBHRG reported evidently causes unsolvable adverse effect on human health and or environment, the Minister shall revoke decision for release and instructs the person or corporoto body holding such decision for release to draw PBHRG from circulation.

## **CHAPTER VII**

### **INSTITUTION**

#### **Part One**

#### **National Commission for Safety of Living Organism and Food**

##### **(KNKHKP)**

#### **Article 28**

To issue certificate of safety of living organism and or food and or feed in performing supervision on circulation and utilization of PBHRG, as well as inspection and verification for the correctness of the report on negative impact as referred to in Articles 22, 25, and 27, the Minister shall be assisted by KNKHKP.

#### **Article 29**

- (1) KNKHKP as referred to in Article 28 has the following duties:
- a. formulate policies and procedure for assessment on the safety of living organism and or food and or feed as well as monitoring of PBHRG;

- b. issue recommendation on the safety PBHRG as consideration material in deciding utilization of PBHRG;
  - c. establishing cooperation and consultation with various institutions inside or outside the country relating to the safety of living organism and or food and or feed of PBHRG;
  - d. evaluate report on the result of assessment on the safety of living organism and or food and or feed of PBHRG;
  - e. prepare relevant information on the implementation of safety of living organism and or food and or feed of PBHRG;
- (2) KNKHKP as referred to in Article 28 has the following authorities:
- a. As clearing house of safety of living organism and or food and or feed of PBHRG at national level;
  - b. Giving recommendation on the appointment of laboratory and limited testing facility of the safety of living organism and or food and or feed meeting the qualifications.
- (3) KNKHKP as referred to in Article 28 has the following obligations:
- a. report to the Minister on the implementation of its duties according to the scope of authorities at least once in a year;

- b. to keep confidentiality of application for assessment on the safety of living organism and or food and or feed of PBHRG;

### **Article 30**

- (1) Members of KNKHKP shall meet the following requirements:
  - a. Indonesian citizen residing permanently in Indonesia;
  - b. Having competency in the field of living organism and or food and or feed.
- (2) Composition of membership of KNKHKP shall consist of:
  - a. Government representative;
  - b. Representative of professional organizations;
  - c. Representative of associations;
  - d. Community.
- (3) Establishment of KNKHKP shall be decided further by virtue of Presidential Decree.

### **Article 31**

- (1) In performing its duties, authorities and obligations, KNKHKP shall be assisted by TTKHKP.
- (2) Membership of TTKHKP shall consist of experts relating to PBHRG.
- (3) TTKHKP has obligation to maintain the confidentiality of application documents for assessment on the safety of living organism and or food and feed.

- (4) Formulation of duties, authorities, and obligations of TTKHKP shall be regulated further by the Minister upon suggestions and considerations of the Chairman of KNKHKP.

## **CHAPTER VIII**

### **SANCTION**

#### **Article 32**

- (1) Any person or compare body that does not comply with instruction to withdraw PBHRG from circulation as referred to in Article 27 paragraph (3) shall be subjected to a sanction pursuant to the prevailing legislation.
- (2) In addition to the sanction as referred to in paragraph (1), business permit of the person or comparete body shall be revoked or proposed to be revoked by the Minister to the issuing official.

#### **Article 33**

Any members of KNKHKP and TTKHKP not performing obligation to keep confidential commercial aspects as referred to in Article 29 paragraph (3) and Article 31 paragraph (3), shall be subjected to a sanction pursuant to the legislation in the field of personnel affairs for government representatives, whereas the other members shall be subjected to a sanction pursuant to the prevailing legislation and fired from membership of KNKHKP and or TTKHKP.

**CHAPTER IX**  
**TRANSITIONAL PROVISIONS**

**Article 34**

Upon the enforcement of this Government Regulation, all laws and regulations relating to the safety of living organism and or food and or feed of PBHRG shall remain valid if not contradictory to or not provided otherwise based on this Government Regulation.

**Article 35**

All applications for release of PBHRG already submitted to the Minister and under process upon validity commencement of this government Regulation, will be processed further based on the provision of the existing legislation.

**CHAPTER X**  
**CLOSING PROVISION**

**Article 36**

This Government Regulation shall come into effect on the date of enactment.

Stipulated in: Jakarta

On:

PRESIDENT OF THE REPUBLIC OF INDONESIA  
**MEGAWATI SOEKARNOPUTRI**

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Translated from the Indonesian Language  
Jakarta, December 11, 2001  
Authorized and Sworn Translator,

**SOFYAN A.S.**