
AUTHORIZED TRANSLATION

PART TWO

DRAFT LAW

NUMBER ..... OF 20

Regarding

SAFETY OF LIVING ORGANISMS OF BIOTECHNOLOGICAL PRODUCTS PRODUCED THROUGH GENETIC ENGINEERING

BY THE GRACE OF THE ONE SUPREME GOD

PRESIDENT OF 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 United Nations *Convention on Biological Diversity* has been ratified by virtue of Law under Number 5 of 1994;

c) that rapid development in science and technology has motivated increased activities in utilizing bio-diversity, biotechnological industry development and improvement in trading, release and circulation of biotechnological

products produced through genetic engineering in the area of health, agriculture, food and feed, plantation and forestry, and industry;

d) that human health, unity and existence of bio-diversity and genetic bio-diversity center is very important for living continuity;

e) that due to limited capacity of a country to overcome adverse effect of biotechnological products on human health and environment

f) that based on the above matters and as the implementation of:

Article 8 point (g) namely developing and maintaining procedures to regulate, manage, or control the risk relating to utilization and release of biotechnological organism which may have adverse effect on environment which may affect continuous conservation and utilization of living organisms in consideration of risk to human beings, and

Article 10 regarding continuous utilization of components of bio-diversity points (b), (c), (d) and (e), then it is necessary to stipulate a Law on Safety of Biotechnological Products produced Through Genetic Engineering.

In view of:

1. Article 5 paragraph (2) of the 1945 Constitution of the Republic of Indonesia;
2. Law Number 2 of 1961 regarding Output and Input of Plants and Seeds;
3. Law number 2 of 1966 regarding Hygiene;
4. Law Number 6 of 1967 on Provisions of Animal Husbandry and Health;
5. Law Number 9 of 1985 regarding Fishery;
6. Law Number 5 of 1990 regarding Conservation of Natural Resources and its Ecosystem;
7. Law Number 12 of 1992 regarding Plant Cultivation System;
8. Law Number 16 of 1992 regarding Animal, Fish and Plant Quarantine;
9. Law Number 23 of 1992 regarding Health;
10. Law Number 5 of 1994 regarding Ratification of *United Nations Convention on Biological Diversity*;
11. Law Number 7 of 1996 regarding Foods;
12. Law Number 23 of 1997 regarding Management of Living Environment;
13. Law Number 8 of 1999 regarding Consumer Protection;
14. Law Number 22 of 1999 regarding Regional Government;

15. Law Number 41 of 1999 regarding Forestry;
16. Law Number 29 of 2000 regarding Protection of Plant Variety.

HAS DECIDED:

To stipulate : LAW OF THE REPUBLIC OF INDONESIA REGARDING SAFETY OF LIVING ORGANISMS OF BIOTECHNOLOGICAL PRODUCTS PRODUCED THROUGH GENETIC ENGINEERING.

CHAPTER I
GENERAL PROVISIONS

Article 1

In this Law, what we mean by:

1. **Biotechnology** shall be technology which utilizes an organism or its part engineered through DNA recombination technique of nucleate acid modification including DNA *in vitro* manner and direct injection of nucleate acid into cell and organ or cell fusion existing beyond taxonomic family.
2. **Biotechnological Products Produced through Genetic Engineering (PPBHRG)** shall be all results of biotechnological activity in the form of living organism or object and all materials processed from organism of genetic engineering, and the derivatives thereof.
3. **Ecosystem** shall be a complex of dynamic relationship happening among plants, animals, microorganisms, non-

biotic environment which mutually interacts to form a functional unit.

4. **Safety of Living Organism** shall be a condition and efforts required to prevent possible emergence of anything that may disturb, harm and endanger human health, biodiversity, and living environment as a result of utilization of transgene organism or materials from transgene organism.
5. **Food Safety** shall be a condition and efforts required to prevent possible emergence of anything that may disturb, harm and endanger human health due to production, storage, circulation and preparation of materials made of trangene organism.
6. **Feed Safety** shall be a condition and efforts required to prevent possible emergence of anything that may disturb, harm and endanger animal and cattle health as a result of production, storage, circulation, and preparation of materials made of transgene organism.
7. **Substantial Equivalent** shall be equivalence based on phenotypic character equivalence among others morphology, growth, result, resistance against disease and etc., and other characters such as nutrition content, carbohydrate, protein, fat, mineral, fiber, ashes, and anti-nutrition compound substantially comparable with non-transgene organism.

8. **Generally Recognized as Safe** shall be a safe condition for consumption applied to food additives.
9. **Allergy** shall be a condition where body gives spontaneous reaction indicating that the consumed food causes refusal reaction by the body.
10. **Export** shall be overseas movement made intentionally from one country to another country.
11. **Exporter** shall be any person or corporate body, under jurisdiction of exporter which regulates export of products of transgene engineering or materials from organism of genetic engineering.
12. **Import** shall be overseas movement made intentionally from one country into another country.
13. **Importer** shall be any person or corporate body which is subject to jurisdiction of importing party regulating import of organism of Genetic Engineering or materials generated from organism of genetic engineering.
14. **Field Testing Facility** shall be any operation conducted in an open field under the condition and other physical structure involving genetic engineering organism controlled by special methods effectively limiting the organism contacting with, and its impact on environment with the purpose of analyzing effects of organism of genetic engineering on living environment.
15. **Limited Field Testing Facility** shall be any operation conducted in an open and limited field (with limitation

of field as required) isolated from general agricultural environment and other physical structures involving organism of genetic engineering control by special methods effectively limiting the organism contacting with, and its impact on environment with the purpose of analyzing effects of organism of genetic engineering on living environment.

16. **Limited Testing Facility** shall be any operation conducted in an installation or other physical structure involving organism of genetic engineering controlled by special methods effectively limiting the organism contacting with, and its impact on environment with the purpose of analyzing effects of organism of genetic engineering on living environment.
17. **Gene** shall be genetic material originating from plant, animal, microorganism or other living organisms which determine living capability or have functional unit to be regenerated.
18. **Intended use** shall be deliberately made or designed purpose.
19. **Risk Assessment** shall be an assessment with the purpose of determining the kind and value of risk as a result of utilization of biotechnological products of genetic engineering on living environment and human beings.
20. **Convention on Biodiversity** shall be a convention made by United Nations on Environment Program (UNEP) in 1992 and

ratified by Indonesian Government by virtue of Law Number 5 of 1994.

21. **National Clearing House** shall be a National Body formed by Government under KMNLH comprising Biodiversity Clearing House and Biosafety Clearing House, assigned to handle export and import licensing for all biotechnological products relating to Advances Informed Agreement based on recommendation from National Competent Authority.
22. **National Competent Authority** shall be an independent national body consisting of all stakeholders (experts from State and Private Universities, Private and State Research Institutions, Religious Figures, Social and Cultural Figures, Economy Actors, and Non-Government Organizations relating to the living safety of biotechnological products of genetic engineering, in charge of performing administrative function in the implementation of Living Safety Protocol.
23. **National Focal Point** shall be Government Agency appointed by KMNLH acting as Liaison Office of Indonesian Government with Secretariat Office of Convention on Biodiversity.
24. **National Scientific Authority** shall be an Independent Body formed by Government with members of experts from state and private universities, private and state research institutions studying and developing biotechnology.

25. **Living Organism** shall be a living unity which is able to transfer or reproduce genetic materials, including sterile, virus, viroid and prion organism.
26. **Transgene organism** shall be a living organism which has undergone genetic engineering on *in vitro* basis.
27. **Limited Usage** shall be any operation conducted in a facility, installation of another physical structure involving organism of genetic engineering controlled by special methods effectively limiting the organism contacting with, and its effect on environment.
28. **Precautionary Approach** shall be principle used in performing safety of living organism in utilizing biotechnological products with sense of responsibility through risk assessment and risk management assessment before utilization is performed.
29. **Risk Assessment** shall be an analysis to determine the type and degree of risk which may arise.
30. **Risk Management** shall be any efforts to be performed if risk determined based on risk assessment really happens.
31. **Cartagena Protocol** shall be Protocol of Living Organism Safety as implementing instrument of Convention on Biodiversity signed on February 23, 2000.
32. **Genetic Engineering** shall be any effort to change order and composition of genetic materials of organism on *in vitro* basis or any other manner impossible to happen in living nature.

Article 2

(1) Law on Living Organism Safety is intended to realize the safety of living organism, safety of food and feed, safety of biodiversity and living environment, as well as safety of living organism in the field of science and technology development in utilization of biotechnology and biotechnological products of genetic engineering.

(2) Law on Living Organism Safety is intended to improve benefit and usefulness of biodiversity, biotechnology and biotechnological products for people's welfare based on principles of living environmental management, consumer protection, social and cultural protection and religious life protection as well as creating certainty for industry world.

Article 3

Principle of law applied in this Law is **Precautionary Principles** to realize safety of living organism, food and feed, human health and environment in consideration of religious norms, ethics, moral and social and cultural condition.

Article 4

Scope of Law on Living Organism Safety shall cover all aspects of safety system of living organism of biotechnological products produced through genetic engineering covering various kinds of biotechnological products, research and development, utilization, circulation and trading including export and import, storage and processing of other products.

CHAPTER II

TYPES OF BIOTECHNOLOGICAL PRODUCTS PRODUCED THROUGH GENETIC ENGINEERING

Article 5

Types of Biotechnological Products Produced through Genetic Engineering

(1) Living organism which has experienced genetic engineering using DNA recombination technology or called transgene organism.

(2) Living organism developed using technique of cell fusion or protoplast fusion where one of or both mother cells is derived from cell developed and using DNA recombination technology.

(3) Living organism developed from cell or cell components containing gene elements is inserted using organelle transfer technique.

(4) Living or dead materials originating from transgene organism.

(5) Material directly obtained from transgene organism or processing material containing insert genes originating from trangene organism.

(6) Such living organism can be in the form of plant, animal and microorganism.

CHAPTER III

TYPE OF UTILIZATION AND INTENDED USE OF BIOTECHNOLOGICAL PRODUCTS OF GENETIC ENGINEERING

Article 6

Biotechnological products produced through Genetic Engineering can be utilized in the following forms:

(1) health field for prevention and treatment of disease, diagnosing disease, health care and genetic therapy.

(2) agricultural field with the purpose of producing food, feed, fiber, and medicines covering seedling and/or grafting.

(3) Plantation field to produce food, feed and fiber materials and medicine material covering seedling and grafting.

(4) Animal Husbandry field to produce food and feed materials and other materials.

(5) Forestry field for the purpose of quality improvement of building materials.

(6) Bio-remedy and/or waste management using microorganism.

(7) Processing of materials originating from trangene organism into other materials.

(8) Processing materials originating from transgene plant for the need of health, food and feed, and other processed materials containing alien products and insert gene.

CHAPTER IV

REQUIREMENTS FOR SAFETY OF BIOTECHNOLOGICAL PRODUCTS PRODUCED THROUGH GENETIC ENGINEERING

Article 7

The materials as referred to in Article 6 from inside or outside the country shall meet requirements for living organism and food safety. Basic information required for requirements of living organism safety shall cover:

(1) Utilization of biotechnological products of genetic engineering imported:

a. name, address, and detailed contacts of exporters;

b. name, address, and detailed contacts of exporters;

c. name and identity of modified living organism (OHM) and domestic classification, if any, at the level of safety of living organism and modified living organism (OHM) in exporting country;

d. date or dates where OHM of boundary crossing is conducted, if notified;

e. taxonomic status, general name, place of collection and taking and characteristics of recipient organism or mother organism relating to living organism safety;

f. Center of origin or genetic diversity center of recipient organism and/or mother organism and description about habitat where the organism can survive, if identified;

g. taxonomic status, general name, place of collection and taking and characteristics of donor organism or organisms relating to living organism safety;

h. Description about nucleate acid or modification made, technique used and characteristics produced from modified organism (OHM);

i. Utilization of modified organism or its products, particularly processed materials generated from modified organism containing genetic material that can be replicated with new combination obtained through modern biotechnology;

j. Number or volume of modified organisms to be transferred across boundary;

k. Report on previous risk assessment or existing risk assessment as contained in Appendix III;

l. Suggested methods for safe handling, storage, transportation and usage, including packaging, documentation labeling, disposal procedure and unexpected things and any contingency suitable for safety;

m. Status of prevailing legislation for modified organism (OHM) in exporting country (for example OHM is forbidden in exporting country, or there are other limitations in its usage, or has obtained approval for free trading) or OHM has been banned in exporting country and what are the reasons for such ban;

n. Result and purpose of notification by exporting country to another country regarding modified organism to be transferred;

o. Declaration or statement that the above information is factually correct.

(2) Utilization of biotechnological products of genetic engineering for further processing:

(a) name and detailed contacts from party applying for decision on domestic usage;

(b) name and address of institution responsible for such decision;

(c) name and identity of modified organism (OHM);

(d) description about gene modification, technique employed, characteristics resulted from modified organism;

(e) any identification sign of modified organism;

(f) taxonomic status, general name, place of collection and taking, and characteristics of organism or mother organism relating to living organism safety;

(g) Center of origin or genetic diversity center of recipient organism and/or mother organism and description about habitat where the organism can live or proliferate;

(h) Taxonomic status, general name, place of collection and taking and characteristics of

donor organism or organisms relating to living organism safety;

(i) Approved usage for modified organism;

(j) Report on risk assessment consistent with Appendix III;

(k) Suggested methods for safe handling, storage, transportation and usage, including packaging, documentation labeling, disposal procedure and related unexpected things.

Article 8

(3) Obligation to contain additional information in the usage and utilization for the need of risk assessment:

a) Risk assessment on **Transgene Microorganism** is conducted in three stages:

Stage I. Transgene Microorganism is divided into three classes:

Class I. Microorganism not relating to human disease

Class II. Microorganism relating to human disease

Class III. Microorganism having potency to cause human disease but the spread can be limited

Class IV. Microorganism which is able to cause serious disease to human being in wide scale.

Stage 2. Evaluation of possible effect on health environment regarding viability and virulence of microorganism

Stage 3. Further evaluation based on data in stage I and Stage 2

b) Evaluation (Risk Assessment) on Trangene Plant is conducted in three stages:

Stage I: Transgene plant can be distinguished in 3 classes based on gene transferability:

Class I : plants with minimum capacity to transfer gene to plants of the same family and sexually incompatible.

Class II : plant with low possibility to perform gene transfer.

Class III : plant with high possibility to perform gene transfer with highly sexual compatibility with local plants.

Stage 2. Transgene plant is distinguished based on competitiveness with habitat in classes, namely:

Class I : minimum competitiveness (minimal advantage)

Class IIa : low competitive capacity (low advantage) namely features which can survive and competitiveness without selective pressure (for example tolerant with herbicides).

Class IIb : low competitive capacity (low advantage), namely features which can survive with

selective pressure such as resistance against pesticides, disease and environmental threats.

Class III : Plants with high competitiveness (high advantage), with features among others enhanced growth and survival in any environmental condition.

Stage 3. Evaluation based on evaluation data of stage 1 and stage 2.

Article 9

(4) Requirements for biotechnological products produced through genetic engineering for use as direct food material or through processing as canned food shall be as follows:

a) nutrition content and quality based on Substantial Equivalent as determined in Code Almentarius with non-transgene products

b) carbohydrate, protein, fat, fiber, ashes, mineral and vitamin content substantially equivalent with non transgene products

c) toxic material content as anti nutrition substance and allergen

d) content of gene and insert gene

e) products as recorded in d) must be decomposed fast by heating in processing or digested fast in human body.

Article 10

(1) All biotechnological products of genetic engineering rejected by exporting country or country of origin shall not be imported or used or utilized inside the country.

CHAPTER V
APPROVAL FOR UTILIZATION, RELEASE AND CIRCULATION OF BIOTECHNOLOGICAL PRODUCTS PRODUCED THROUGH GENETIC ENGINEERING

Article 11

(1) Before one type of biotechnological product of genetic engineering is used or utilized, the product shall obtain approval for release, usage and utilization from the **National Clearing House.**

(2) To issue the approval, the National Clearing House as referred to in Article 12 paragraph (1) shall consider suggestions from independent **National Competent Authority** authorized by the Government.

Article 12

(1) In the frame of National Clearing House as referred to in article 12 paragraph (2), the Board shall be based on command and consideration of the inspection result which is conducted by certified Test Laboratory and given authority by government.

(2) In the event that the requirement and information as referred to in Articles 8, 9 and 10 are deemed adequate, assessment and retest shall be conducted.

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Article 13

(1) Accredited laboratory as referred to in Article 13 paragraph (1) shall be based on:

a) human resources having scientific competency

b) appropriate infrastructure and facility

c) having capability to perform valid laboratory testing method.

Article 14

(1) All biotechnological products of genetic engineering either directly or indirectly shall obtain Permit for release, circulation, trading, including planting and maintenance in open land.

(2) All processed products packaged and made of transgene organism shall be labeled indicating that the producer uses material from transgene organism.

(3) Biotechnological products as referred to in Article 15 Paragraph (2) are sold at retail and wholesale level.

(4) Label as referred to in Article 15 paragraph (3) shall be easily visible and become one with packaging.

(5) Every agency, either private or government, in performing import and/or export of biotechnological products produced

through genetic engineering shall obtain approval from the National Clearing House before transaction is done.

(6) In case of failure on this case as referred to in Article 15 paragraph (5), the person in charge of the products shall be subjected to sanction according to the prevailing legislation.

(7) In case after the issue of permit for circulation and release biotechnological products are found to cause adverse effect on human health and living environment, then the competent authority shall stop the circulation at the expense of responsible party.

CHAPTER VI
LIVING ORGANISM SAFETY TEST

Article 15

(1) Biotechnological product of genetic engineering used and utilized in open space shall be subject to LIVING ORGANISM SAFETY TEST IN STAGES starting with Living Organism Test in closed Confinement Facility pursuant to international standard followed by Limited Field Test and wider Field Test.

(2) Wider Limited Field Testing means the size of area and testing location.

(3) Limited Test Field shall not directly contact with land already used by the community.

Article 16

(1) Information obtained from each testing of living organism safety shall be transparent and accessible by experts, universities, research institutions, and competent social organizations.

CHAPTER VI
INSTITUTIONALIZATION, AUTHORITY, SUPERVISION AND CONTROL

Article 17

(1) Supervision on the Institutions as referred to in Article 12 shall be conducted by Presidential Institution or Minister appointed by President.

(2) Institution performing living organism testing shall be appointed by an independent National Competent Authority authorized by the Government.

(3) The National Competent Authority shall give directive to any institution having authority to perform living organism safety testing.

(4) The bodies as referred to in Article 12 shall cooperate with other relating institutions.

CHAPTER VII
RESEARCH AND DEVELOPMENT

Article 18

(1) The Government supports participation of all components of Community to conduct research and development of

biotechnological products produced through genetic engineering inside the country to meet welfare and need of the community.

(2) The Government supports development of biotechnological industry in the country to open opportunity for export of biotechnological products of genetic engineering.

(3) Biotechnological products of genetic engineering as referred to in Article 18 shall comply with requirements for living organism safety.

(4) Any performance of research and development of biotechnological products of genetic engineering which may harm human health and environment shall be prevented and overcome.

(5) Research and development of biotechnological products of genetic engineering shall be supervised by the National Scientific Authority.

CHAPTER VIII
TRANSITIONAL PROVISION

Article 19

Upon the enforcement of Law on Safety of Living Safety of Biotechnological Products Produced Through Genetic Engineering, all laws and regulations relating to Living Safety including Safety of Food, Feed and other products contradictory to this Law shall be amended and adjusted to the above Law.

CHAPTER IX

CONCLUDING PROVISION

Article 20

Law on Living Safety of Biotechnological Products produced through Genetic Engineering shall come into effect on the date of promulgation.

Stipulated in Jakarta

On .....

HOUSE OF REPRESENTATIVES OF THE REPUBLIC OF INDONESIA

SPEAKER,

( )

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

SOFYAN A.S.