

Courtesy translation

Regulation of the Government of the Republic Indonesia Number 21 Year 2005
on Biosafety of Genetically Engineered Product

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<p>REGULATION OF THE GOVERNMENT OF THE REPUBLIC OF INDONESIA NUMBER 21 YEAR 2005</p> <p>ON</p> <p>BIOSAFETY OF GENETICALLY ENGINEERED PRODUCT</p> <p>With the Bless of God the Almighty</p> <p>THE PRESIDENT OF THE REPUBLIC OF INDONESIA</p>	
<p>Considering: that to implement the provision of Article 8 paragraph (2) letter (b) and paragraph (3) of Law Number 23 of 1997 on Environmental Management, it is necessary to have a Government Regulation on Biosafety of Genetically Engineered Product.</p>	<p>1. GENERAL</p> <p>Indonesia is one of nations in the world having biological diversity with high value. The biological diversity represents the bless and bounty of the God Almighty and that it is necessary to have a sustainable management to improve the community welfare without affecting to human and environmental health.</p>

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	<p>The use of biological diversity through modern biotechnology resulting in Genetically Engineered Product (GEP) has provided an opportunity to support agricultural production, food availability, and improvement of human life quality. Modern biotechnology used in producing GEP includes in-vitro nucleic acid and cell fusion. The Deoxyribose Nucleic Acid hereinafter abbreviated to DNA, means molecule consisting of for type of base and phosphate sugar frame, which lead to this organism genetic information. Application of this Technology provides such benefits as stepping up production, and enhancing protection against pest and disease and improving protection against environmental stress. However, the application of this technology may create some risk on Environment, biological diversity and human health. The possible risk needs to be minimized through precautionary approach.</p> <p>The possible risk in the application in development of GEP was discussed since negotiation on international agreement draft on biological diversity in 1990, which was adopted later in Convention on Biological Diversity/CBD in 1992. In 1994 the convention was ratified with Law number 5 of 1994. The convention provides, among other things safety in applying modern biotechnology namely in clause of Article</p>

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	<p>8 letter g and Article 19 paragraph (1) which obliges every Convention member country to make, regulate and implement laws on biosafety which also covers foods safety and/or animal feed safety.</p> <p>This Government Regulation is required because the existing legislations do not sufficiently regulate everything on GEP as required in the Convention, and that a systematic and effective arrangement is needed. This government Regulation will serve as legal basis in providing biosafety, food safety and animal feed safety of GEP for the welfare of people based on principle of health and biological resource management, consumer protection and business certainty by putting religion, ethic, social, culture and esthetic into consideration.</p> <p>This government regulation include regulation on: type and requirement of GEP, research and development of GEP, importation of GEP from foreign country, assessment, release, and distribution and use of GEP, control of GEP, institutional framework and cost.</p> <p>This government regulation asides from serving as further implementation of the provision of Article 8 paragraph 2 letter b and paragraph 3 of Law Number 23/1997 on Environmental Management, also related to various Laws.</p>

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	<p>A number of regulation related to and support the government regulation includes:</p> <ul style="list-style-type: none"> a. Law Number 6 of 1967 on Principles of animal husbandry (State Gazette of 1967, Number 10, Supplement to State Gazette Number 2824); b. Law Number 5 of 1984 on Industry (State Gazette of 1984, Number 22, Supplement to State Gazette Number 3274); c. Law Number 5 of 1990 on Natural Conservation of Biological Resource and its Ecosystem (State Gazette of 1990, Number 49, Supplement State Gazette Number 3419); d. Law Number 12 of 1992 on Plant Cultivation System (State Gazette of 1992, Number 46, Supplement to State Gazette Number 3478); e. Law Number 16 of 1992 on Animal, Fish, and Plant Quarantine (State Gazette of 1992, Number 56, Supplement to State Gazette Number 3482); f. Law Number 23 of 1992 on Health (State Gazette of 1992, Number 100, Supplement to State Gazette Number 3495); g. Law No. 5 of 1994 on Ratification of UN Convention on Biological Diversity);

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	<ul style="list-style-type: none"> <li data-bbox="1160 229 1879 309">h. Law No. 7 of 1994 on Ratification of Agreement Establishing the WTO; <li data-bbox="1160 328 1879 464">i. Law Number 7 of 1996 on Food (State Gazette of 1996, Number 99, Supplement to State Gazette Number 3656); <li data-bbox="1160 483 1771 512">j. Law No., 8 of 1999 on Consumers Protection. <li data-bbox="1160 531 1879 667">k. Law Number 41 of 1999 on Forestry (State Gazette of 1999, Number 167, Supplement to State Gazette Number 3888); <li data-bbox="1160 686 1879 821">l. Law number 29 of 2000 on Plant Variety Protection (State Gazette of 2000, Number 241, Supplement to State Gazette Number 4043); <li data-bbox="1160 841 1879 1024">m. Law Number 18 of 2002 on National System of Research, Development and Application of Science and Technology (State Gazette of 2002, Number 84, Supplement to State Gazette Number 4219); <li data-bbox="1160 1043 1879 1179">n. Law No. 18 of 2004 on Plantation (State Gazette of 2004, Number 85, Supplement to State Gazette Number 4414); <li data-bbox="1160 1198 1879 1382">o. Law No. 21 of 2004 on Ratification of Cartagena Protocol to the CBD convention (State Gazette of 2004, Number 88, Supplement to State Gazette Number 4414);

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	<p>p. Law No. 31 of 2004 on Fishery; (State Gazette of 2004, Number 118, Supplement to State Gazette Number 4433);</p> <p>q. Law No.32 of 2004 on Regional Government (State Gazette of 2004, Number 125, Supplement to State Gazette Number 4437);</p>
<p>In view of:</p> <ol style="list-style-type: none"> 1. Article 5 paragraph (2) of the 1945 Constitution of the Republic of the Indonesia. 2. Law Number 5 of 1994 on Ratification of United Nations Convention on Biological Diversity (State Gazette of 1994 Number 41 Supplement to State Gazette Number 3556); 3. Law Number 23 of 1997 on Environmental Management. 	
<p style="text-align: center;">DECIDED</p> <p>To stipulate: REGULATION OF GOVERNMENT OF THE REPUBLIC OF INDONESIA ON BIOSAFETY OF GENETICALLY ENGINEERED PRODUCT.</p>	
<p style="text-align: center;">CHAPTER 1 GENERAL PROVISION</p>	<p style="text-align: center;">II. ARTICLE BY ARTICLE</p>

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<p style="text-align: center;">Article 1</p> <p>In this Government Regulation the following terminologies shall mean:</p> <p>1. Biosafety of genetically engineered product means environmental safety, food safety and/or animal feed safety of genetically engineered product.</p>	<p>Article 1</p> <p>Self-explanatory</p>
<p>2. Environmental safety means condition and effort required to prevent any possible occurrence of impact which may affect biological diversity as a result of the use of genetically engineered product.</p>	
<p>3. Food safety of genetically engineered product means condition and effort required to prevent any possible occurrence of impact which may affect and endanger human health, as a result of process of production, preparation, storage, distribution and use of food of genetically engineered product.</p>	
<p>4. Food means everything originated in biological source and water, whether or not processed which serves as food or drink for human to consume, including food supplement, food raw material and other material used in the process of preparation, processing and or making of food and drink.</p>	

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5. Feed safety of genetically engineered product means condition and effort required to prevent any possible occurrence of impact which may affect and endanger animal and fish health as a result of process of production, preparation, storage, distribution and use of animal feed of genetically engineered product.	
6. Animal feed means raw material, additional material, and supplemental material or its mixture originating in biological, mineral and water source whether not processed which serves as animal feed and or fish food.	
7. The genetically engineered (GE) product hereinafter referred as to GEP (PRG) means a living organism, parts thereof and or its result of process which has composition of new genetics as result of modern biotechnology application.	
8. Modern biotechnology means the application of genetic engineering technique consisting of in-vitro nucleic acid techniques and fusions of cells beyond the taxonomic family.	
9. GE animal means animal resulted from genetically engineered technique application which greater or the whole part thereof lives on land.	
10. Material made from GE animal means any material resulted from GE animal that can be processed further for the need of human and	

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other purpose.	
11. Product made from GE animal means product made from material resulted from GE animal which is processed with or without using additional material.	
12. GE fish means fish resource and other water biota species which the whole or part of its lifecycle is in the water and is resulted from genetically engineered technique application.	
13. Material made from GE fish means any material resulted from GE fish which can be further purchased for the human's and other purpose.	
14. Product made from GE fish means product resulted from GE fish material which is processed by certain way or method with or without using additional material.	
15. GE plant means plant resulted from genetically engineered technique application.	
16. Material made from GE plant means material resulted from GE plant and can be further processed for human's or other purpose.	
17. Product of material resulted from GE plant means product	

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<p>originated in material resulted from GE plant which can be processed with or without using additional material.</p>	
<p>18. GE microorganism means microorganism resulted from genetically engineered technique application.</p>	
<p>19. Material made from GE microorganism means body/cell of GE microorganism and or its metabolism product.</p>	
<p>20. Product of material resulted from GE microorganism means product resulted from material originated in body/cell of GE microorganism or its metabolism product which processed by way or certain method with or without using additional material.</p>	
<p>21. Risk assessment of GEP means assessment of possible occurrence of influence that can affect environment, human health and animal health as a result of GEP development and use based on correct scientific method and certain statistic.</p>	
<p>22. Assessment means the whole process of document verification and test of GEP and related social and economic factor.</p>	
<p>23. Test means evaluation and technical assessment of GEP consisting of engineering technique, efficacy and requirement of biosafety in laboratory, limited test facility, and or limited test field.</p>	

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24. Biosafety Commission of Genetically Engineered Product hereinafter referred to as BC (KKH) means commission assigned to assist Minister in making and providing policy and issue GEP biosafety certificate.	
25. Biosafety Safety Clearing House of Genetically Engineered Product hereinafter referred to as IBCH (BKKH) means an element of BC serving as communication facility between BC and stakeholder.	
26. Biosafety Technical Team of Genetically Engineered Product hereinafter referred to as BTT (TTKH) means team assigned to assist BC in conducting evaluation and technical assessment of biosafety and GEP use feasibility.	
27. Notice means information delivery to the public on the result of the evaluation and technical assessment of GEP biosafety through BC official news and notice board or mass media prior to granting of GEP biosafety recommendation by BC.	
28. Person means individual person and or a group of person and or legal entity.	
29. Applicant means person asking for the license with the competent Minister and/or Chairman of Non-Departmental Agency (LPND) authorized to release and/or distribute GEP.	

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30. Release means statement on admission of a result of breeding for excellent variety and can be distributed following the fulfillment the requirement based on relevant legislation.	
31. Distribution means any activity or series of activity in distributing commodity to people whether or not in the trade.	
32. Competent Minister means Minister whose scope of duty covers the area of delivery and distribution of GEP.	
33. Head of competent Non-Departmental Agency hereinafter referred to as the Head of competent LPND means Head of LPND whose scope of duty covers distribution of GEP.	
34. Day means calendar days.	
35. Minister means Minister of Environment.	
Article 2	Article 2
(1) The purpose of this Government Regulation is to contribute to ensuring adequate level of environmental safety, food safety and or animal feed safety of GEP and its use in the area of agriculture, fishery, forestry, industry, environment and non-pharmaceutical health.	Self-explanatory
(2) The purpose of this government regulation is to improve efficiency	

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<p>and effectiveness of GEP use for people welfare based on principle of health and biological resource management, consumer protection and certainty in operating business.</p>	
<p style="text-align: center;">Article 3</p> <p>This government regulation is based on the precautionary approach to contribute to ensuring environmental safety, food safety and or animal feed safety based on an accurate scientific method by considering religious, ethic, socio-cultural and esthetic norms.</p>	<p>Article 3</p> <p>Precautionary approach means an approach in making decision on preventive action against possible impact which may lead to a significant impact on environment and human health, even before conclusive scientific evidences are found with respect to that impact. In this government regulation the precautionary approach shall be implemented as such provided that prior to a GEP is implemented a biosafety assessment and or food safety and or animal feed safety (risk assessment and management) will need to be conducted by using an accurate scientific method by considering social, economic, and ethical factors to guarantee that the risk of using GEP on environment and human health shall be acceptable based on the existing regulation. Consideration in term of religion, ethic, socio culture among others genes transformed into GEP shall not coming from organism violating certain religious norms accepted in the country, shape or phenotype of GEP animal should equal to its parental in line with prevailing esthetic norm.</p>

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<p style="text-align: center;">Article 4</p> <p>Scope of this Government Regulation includes provision on:</p> <ul style="list-style-type: none"> a. type and requirement of GEP; b. research and development of GEP; c. importation of GEP from abroad; d. assessment, release and distribution and use of GEP; e. supervision and control of GEP; f. institution; g. finance; h. Provision on sanction. 	<p>Article 4</p> <p style="text-align: center;">Self-explanatory</p>
<p style="text-align: center;">Chapter II</p> <p style="text-align: center;">TYPE AND REQUIREMENT OF GEP</p>	
<p style="text-align: center;">Section One</p> <p style="text-align: center;">Type of GEP</p>	
<p style="text-align: center;">Article 5</p> <p>Type of GEP includes:</p> <ul style="list-style-type: none"> a. GE animal, material resulted from GE animal and its product; b. GE fish, material resulted from GE fish and its product; c. GE plant, material resulted from GE plant and its product; and d. GE microorganism, material resulted from GE microorganism and its product; 	<p>Article 5</p> <p>not including : wild animals, protected fish included in CITES appendix, & wild plants.</p>
<p style="text-align: center;">Section two</p> <p style="text-align: center;">Requirement of GEP</p>	

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<p style="text-align: center;">Article 6</p> <p>(1) GEP be it originates in country or imported, intended to be submitted for an assessment for trial or commercial release in Indonesia must be provided with basic information as guide that the product fulfills requirement of environmental safety, food safety and or animal feed safety</p>	<p>Article 6</p> <p>Paragraph (1)</p> <p style="padding-left: 40px;">Self-explanatory</p>
<p>(2) The basic information as guide to fulfilling requirement of environmental safety as referred to in paragraph (1) shall include among others:</p> <ul style="list-style-type: none"> a. Description and purpose of use; b. Change of genetics and phenotype expected to detect; c. Clear identity on taxonomy, physiology, and reproduction of GEP. d. Organism used as source of gene must clearly be stated. e. Genetically engineered method used shall comply with standard protocol that can be justified scientifically. f. Molecular characteristic of GEP must be clearly stated g. Gen expression transformed into GEP must be stable in subsequent generations. h. Applied manner of destruction in case of irregularity. 	<p>Paragraph 2</p> <p>Letter a</p> <p style="padding-left: 40px;">Self-explanatory</p> <p>Letter b</p> <p style="padding-left: 40px;">Self-explanatory</p> <p>Letter c</p> <p style="padding-left: 40px;">Self-explanatory</p> <p>Letter d</p> <p style="padding-left: 40px;">Gene source shall clearly and completely be stated means that its origin in obtaining organism used as gene source which protection status must also be clear (protected or not), including Appendix CITES (I, II and III) or not. Be stated in the appendix CITES, must be in full set of document/certificate in term of its origin.</p> <p>Letter e</p> <p style="padding-left: 40px;">Self-explanatory</p>

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	<p>Letter f Must clear shall mean the assessment shall comply with molecular characteristic assessment guide.</p> <p>Letter g Self-explanatory</p> <p>Letter h Self-explanatory</p>
<p>(3) Basic information serving as guide to fulfilling requirement of food safety and animal feed safety as referred to in the paragraph (1) shall include among others:</p> <p>a. Genetically engineered method used shall comply with standard protocol that can be justified scientifically.;</p> <p>b. GEP nutrient content shall substantially be equivalent to that of non-GEP;</p> <p>c. Hazardous compound, nutrient-resistant and allergic-inducing content in the GEP shall substantially be equivalent to that of non-GEP.</p> <p>d. Carbohydrate, protein, dust, fat, fiber, amino acid, fat acid and vitamin content in the GEP shall substantially be equivalent to that of non-GEP.</p> <p>e. Protein encoded by the introduced gene should not be allergen in nature.</p> <p>f. Applied manner of destruction in case of irregularity.</p>	<p>Paragraph (3)</p> <p>Letter a Self-explanatory</p> <p>Letter b Substantial equivalence means a condition in which a transgenic product shall substantially be equivalent to non-transgenic product in term of its origin except the engineered properties in interest.</p> <p>Letter c Hazardous compound content means a compound naturally existing in plant such as <i>trypsin inhibitor</i>, <i>lectin</i>, <i>urease</i> in soybean, which is not soil bacteria toxin <i>Bacillus thuringiensis</i> which may cause a certain species of ant to die.</p> <p>Letter d Self-explanatory</p>

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	Letter e Self-explanatory Letter f Self-explanatory
<p style="text-align: center;">Article 7</p> <p>Provision on details of type of GEP, requirement for environmental safety and requirement for food safety and or animal feed safety shall further be provided by the Minister, competent Minister or Head of competent LPND according to their respective areas.</p>	<p style="text-align: center;"><i>Article 7</i></p> <p>Basic provision made includes among others the purpose of use of the GEP.</p>

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CHAPTER III RESEARCH AND DEVELOPMENT OF GEP	
<p style="text-align: center;">Article 8</p> <p>Any person conducting research and development of GEP shall prevent and or eradicate any negative impact of their activities on human and environment</p>	<p>Article 8</p> <p style="text-align: center;">Self-explanatory</p>
<p style="text-align: center;">Article 9</p> <p>Test of GEP during the process of research and development shall be conducted in a laboratory, limited test facility and or limited test field.</p>	<p>Article 9</p> <p style="text-align: center;">Self-explanatory</p>
<p style="text-align: center;">Article 10</p> <p>GEP resulted from a research and development activity as referred to in the Article 9 before it is proposed for release and or distribution must be tested for its efficacy and fulfill biosafety requirement.</p>	<p>Article 10</p> <p>Test for efficacy shall be intended to make sure that gene interest transformed into GEP is correctly expressed.</p>
<p style="text-align: center;">Article 11</p> <p>(1) Government shall develop the role of all components of communities to support research and development to produce GEP in country.</p>	<p>Article 11</p> <p>Paragraph (1)</p> <p style="text-align: center;">Self explanatory</p>
<p>(2) In developing the role of all components of communities as</p>	<p>Paragraph (2)</p>

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referred to in paragraph (1), the Government may give appreciation to the community who can produce new GEP which is beneficial to the interest of the state.	Self-explanatory
(3) In the event that the community has yet to be able to play its role in conducting research and development of GEP, the Government shall conduct research and development to produce GEP.	Paragraph (3) Self-explanatory
<p style="text-align: center;">Article 12</p> <p>1. GEP research and development shall be conducted based on the legislation in the area of national system of research, development and application of science and technology.</p> <p>2. Procedure for implantation of GEP research and development as mentioned in paragraph (1) above shall further be provided by competent Minister or Head of LPND.</p>	Article 12 Self-explanatory
CHAPTER IV IMPORTATION OF GEP FROM ABROAD	

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<p style="text-align: center;">Article 13</p> <p>(1) Any person who imports any GEP of the same type from abroad for the first time, shall sub application to the competent Minister or Head of designated competent LPND (national non departmental org)</p>	<p>Article 13</p> <p>Paragraph (1)</p> <p>GEP of the same type means the same genetically engineered GEP including that of resulted from conventional crossbreeding. The same variety of different GEP result is not classified as the GEP of the same type.</p> <p>The GEP of the same type shall be tested for its biosafety only for its first time importation. Once it meets requirement of biosafety, subsequent importation of GEP for the same type shall no need be tested for its biosafety. Permit from the Minister shall only be required for the first time importation of GEP.</p> <p>The application as referred to in this paragraph shall also serve as notification from person who desires to import such GEP to the relevant Minister or Chairman of LPND for its biosafety test in a bid to obtain a certificate of biosafety as one of requirement for release and distribution of the relevant GEP.</p>
<p>(2) The application for importation of GEP shall, as referred to in the Article 6, be provided with document stating that the requirement of environmental safety, food safety, and or animal</p>	<p>Paragraph (2)</p> <p style="text-align: center;">Self-explanatory</p>

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feed safety has been fulfilled.	
<p>(3) In addition to fulfilling the requirement as referred to in the paragraph (2), the importation of GEP from abroad shall also be provided with:</p> <ul style="list-style-type: none"> a. Certificate of free trade stating that the GEP has been in the free trade in its country of origin; and b. Assessment document and risk management of a competent authority at which the risk management was once conducted. 	<p>Paragraph (3)</p> <p>Self-explanatory</p>
<p>(4) After receiving application as referred to in the paragraph (1), the competent Minister or the Head of LPND shall then:</p> <ul style="list-style-type: none"> a. check for the full set of document and fulfilling of requirement as referred to in the paragraph (2) and paragraph (3); b. within no later than 15 (fifteen) days as of receipt of the application, notify the applicant on the full set of document and requirement that shall be fulfilled by the applicant in accordance with legislation applicable to importation of GEP. 	<p>Paragraph (4)</p> <p>In addition to the full set of certificate stating that the GEP has been in the free trade in its country of origin and assessment document and risk management, the importation of GEP form abroad, other applicable legislation shall also need to be considered.</p>
<p>(5) In the event that the document and requirement as referred to in the paragraph (2) and paragraph (3) have been completed, the competent Minister or the Head of competent LPND shall request an environmental safety recommendation with the</p>	<p>Paragraph (5)</p> <p>Self-explanatory</p>

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Minister.	
(6) The competent Minister or Head of competent LPND shall use the biosafety recommendation issued by the Minister of the Head of BC as basis for his/her decision.	Paragraph (6) <ul style="list-style-type: none"> ▪ For variety release, the Competent Minister is Minister of Agriculture; ▪ For fish release: Minister of Marine and Fisheries; ▪ For forest trees: Minister of Forestry; ▪ For processed food release: Head of competent LPND is the Head of Food and Drug Control Agency (BPOM)
(7) The provision on the requirement and procedure for importation of GEP from abroad shall further be provided by the competent Minister or Head of competent LPND.	Paragraph (7) <p>Basic provision on requirement and procedure for importation of GEP from abroad issued by the Minister shall inter alia include the compliance with regulation in the area of quarantine.</p>
CHAPTER V ASSESSMENT, RELEASE AND DISTRIBUTION, AS WELL AS USE OF GEP Section One Assessment Procedure	

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<p style="text-align: center;">Article 14</p> <p>(1) Assessment of GEP shall be conducted prior to release and distribution</p>	
<p>(2) Assessment shall be conducted based on a written application submitted by the applicant to the competent Minister or the Head of competent LPND.</p>	<p>Article 14</p> <p style="text-align: center;">Self-explanatory</p>
<p>(3) After receiving application as referred to in the paragraph (2), the competent Minister or the Head of competent LPND shall, within no later than 14 days, submit application for recommendation of biosafety to the Minister or Head of BC.</p>	
<p style="text-align: center;">Article 15</p> <p>(1) In providing recommendation of biosafety of GEP as referred to in Article 14 paragraph (3), the Minister, competent Minister or the Head of competent LPND shall assign BC to conduct assessment.</p> <p>(2) Maximum period of the assessment as referred to in the paragraph (1) shall be 14 days as of receipt of the letter of assignment.</p> <p>(3) In the event that the assessment relates to technical evaluation, BC shall, if deemed necessary, assign BTT to conduct assessment of technical document and advanced test.</p>	<p>Article 15</p> <p>Paragraph (1)</p> <p style="text-align: center;">Self-explanatory</p> <p>Paragraph (2)</p> <p style="text-align: center;">Self-explanatory</p> <p>Paragraph (3)</p> <p>Period for conducting advanced test at laboratory, limited test facility (greenhouse, cage, pool) and limited test field shall be based on the type</p>

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	and nature of the GEP being assessed.
<p>(4) The period for technical document assessment as referred to in the paragraph (3) shall be conducted no later than 56 days as of receipt of the letter of assignment from BC.</p> <p>(5) Result of technical evaluation and assessment of GEP Biosafety conducted by BTT shall, within no later than 7 days after completion of the technical evaluation and assessment, be delivered to BC as material for proposing recommendation of GEP biosafety.</p>	<p>Paragraph (4)</p> <p>Self-explanatory</p> <p>Paragraph (5)</p> <p>Self-explanatory</p>
<p style="text-align: center;">Article 16</p> <p>(1) The result of the technical evaluation and assessment submitted to BC as referred to in the Article 15 paragraph (5) shall, within no later than 15 (fifteen) days, IBCH announce the receipt of the application, process and summary of the risk assessment at IBCH website accessible to community for 60 days to provide the community with opportunity to give response.</p>	<p>Article 16</p> <p>Self-explanatory</p>
<p>(2) Information that can be given as referred to in the paragraph (1) shall exclude information which is commercial in nature relating to the Intellectual Property Right (HKI) and does not relate to biosafety.</p>	
<p>(3) In the event that during the period of announcement as referred to</p>	

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<p>in the paragraph (1), no community gives response thereto, the community shall be deemed to have no objection to the proposed recommendation from BC.</p> <p>(4) Upon completion of the period of the announcement as referred to in the paragraph (1), IBCH shall, within no later than 7 days, submit report on community response to BC.</p> <p>(5) BC shall, within no later than 14 days as of receipt of the report from IBCH, submit the proposed recommendation of environmental safety and or animal feed safety to the competent Minister or Head of competent LPND.</p>	

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<p style="text-align: center;">Article 17</p> <p>(1) In serving GEP Biosafety recommendation to the Minister, competent Minister or Head of competent LPND, Head of BC shall take notice of the recommendation proposed by BTT and input from the community.</p> <p>(2) In the event that the said GEP is a commodity to be released to environment, the Minister shall, within no later than 14 days as of receipt of the proposed recommendation from BC, serve the environmental safety recommendation to the competent Minister or the Head of competent LPND.</p>	<p>Article 17</p> <p style="text-align: center;">Self-explanatory</p>
<p style="text-align: center;">Article 18</p> <p>(1) The written application as referred to in the Article 14 paragraph (2) shall be provided with document as referred to in Article 6 paragraph (2) and paragraph (3).</p>	<p>Article 18</p> <p style="text-align: center;">Self-explanatory</p>
<p>(2) Checking of document as referred to in the paragraph (1) shall be conducted for:</p> <ul style="list-style-type: none"> a. administrative completeness; b. substantive information; c. additional information on species to be tested, such as: <ul style="list-style-type: none"> i. specific purpose of the test and location, habitat and 	

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<p>ecology;</p> <p>ii. explanation on GEP genetics, experiment procedure, monitoring, data and genetic stability; and</p> <p>d. applicant identity including deed of establishment/legality and taxpayer reference number (NPWP).</p>	
<p style="text-align: center;">Article 19</p> <p>(1) The applicant shall conduct environmental safety test conducted at laboratory, limited test facility and or limited test field for the GEP which application is submitted for release and or distribution to the environment for the first time.</p>	<p>Article 19</p> <p>Paragraph (1) Test in laboratory, limited test facility and or limited test field shall be conducted if the information in the document served by the applicant fails to convince BC to make a conclusion to grant a recommendation on environmental safety and or food safety and or animal feed safety of GEP.</p>
<p>(2) The applicant shall conduct food safety test at laboratory for GEP which application is submitted for the first time distribution.</p> <p>(3) The applicant shall conduct animal feed safety test at laboratory, limited test facility, and or limited test field for GEP which application is submitted for first time distribution.</p>	<p>Paragraph (2)</p> <p style="text-align: center;">Self-explanatory</p> <p>Paragraph (3)</p> <p style="text-align: center;">Self-explanatory</p>

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<p style="text-align: center;">Article 20</p> <p>(1) Biosafety test as referred to in the Article 19 shall be conducted by a competent institute.</p> <p>(2) The institute as referred to in the paragraph (1) shall fulfill the following requirement:</p>	<p>Article 20</p> <p>Paragraph (1)</p> <p>Competent agency means inter alia University, Research Agency having sufficient facility and capability.</p>
<p>a. having a human resources capable of conducting test for environmental safety, food safety and or animal feed safety of GEP; and</p> <p>b. having access to accredited laboratory and limited test facility.</p>	<p>Paragraph (2)</p> <p>Self-explanatory</p>
<p>(3) Laboratory and limited test facility as referred to in the paragraph (2) point b shall:</p> <p>a. have sufficient facility and equipment;</p> <p>b. use an acceptable and safe test method for environmental safety, food safety and or animal feed safety of GEP in accordance with biosafety test guide; and</p> <p>c. ensure the correctness of the test result.</p>	<p>Paragraph (3)</p> <p>Limited test facility means facility which has fulfilled the minimum requirement for conducting biosafety test.</p>
<p>(4) Biosafety test guide as referred to in the paragraph (3) point b shall further be provided by the Minister, competent Minister or Head of competent LPND according to their main duties and functions.</p>	<p>Paragraph (4)</p> <p>Self-explanatory</p>

CONTENT	EXPLANATION
<p style="text-align: center;">Article 21</p> <p>(1) BC shall assign IBCH to publicize the summary of the result of GEP assessment conducted by BTT through mass media both printed and electronic in addition to official news by BC for 60 days as of receipt of the technical assessment from BTT.</p>	<p>Article 21</p> <p>Paragraph (1)</p> <p>The publication is intended to let the community know about the application for release and distribution of GEP. With such a publication, the community can get opportunity to give its response in writing to BC. Publication shall be carried out by inserting it in any publication media provided by BC or through IBCH that is easily made available to the community.</p>
<p>(2) During the publication period as referred to in the paragraph (1), community shall have opportunity to give its response in writing to BC.</p> <p>(3) Response from the community as referred to in the paragraph (2) served to BC beyond the period as referred to in the paragraph (1) shall not be accepted as material for consideration.</p> <p>(4) Based on the result of BTT's assessment and input from the community, BC shall propose its recommendation on:</p> <ul style="list-style-type: none"> a. safety condition of GEP environment to the Minister; b. safety condition of GEP food and or animal feed to the competent Minister and or Head of competent LPND. 	<p>Paragraph (2)</p> <p style="text-align: center;">Self-explanatory</p> <p>Paragraph (3)</p> <p style="text-align: center;">Self-explanatory</p> <p>Paragraph (4)</p> <p style="text-align: center;">Self-explanatory</p>
<p>(5) GEP which passed assessment test shall be provided with a</p>	<p>Paragraph (5)</p>

CONTENT	EXPLANATION
<p>certificate of test result of environmental safety, food safety, and or animal feed safety by BC and be served to the Minister along with the proposed recommendation as referred to in the paragraph (4).</p>	<p>As of the assessment period, response and input from the community has expired, BC shall serve to the Minister, the material for biosafety recommendation.</p>
<p>(6) In case of failure in the assessment test, BC shall serve to the Minister, the proposed recommendation of such a failure along with the reason thereof.</p>	<p>Paragraph (6) Self-explanatory</p>
	<p>Article 22</p> <p>Basic rules on the procedure of GEP safety test includes, among others, procedure on application for test of biosafety and or food safety and or animal feed safety of GEP, procedure for conducting the test, making of recommendation, and period of assessment.</p>

CONTENT	EXPLANATION
<p style="text-align: center;">Article 22</p> <p>(1) Based on the proposed recommendation on the environmental safety, food safety and or animal feed safety as referred to in Article 21 paragraph (4):</p> <p>a. The Minister shall submit recommendation on environmental safety to the competent Minister or Head of competent LPND, provided with certificate of environmental safety;</p> <p>b. BC shall submit the recommendation of food safety and or GEP food safety to the competent Minister or Head of competent LPND, provided with certificate of food safety and or animal feed safety of GEP;</p> <p>(2) Competent Minister or Head of competent LPND shall use the certificate and recommendation mentioned in the paragraph (1) as basis for consideration for the issuance of Decree on the Release and or Distribution of the said GEP, in accordance with applicable legislations.</p>	<p>Article 23</p> <p style="text-align: center;">Self-explanatory</p>
<p style="text-align: center;">Section Two</p> <p style="text-align: center;">Release and Distribution of GEP</p> <p style="text-align: center;">Article 23</p> <p>For GEP which has already received its recommendation of biosafety,</p>	<p>Article 24</p> <p>The decision for release and or distribution of GEP shall comply</p>

CONTENT	EXPLANATION
the decision for its release and or distribution shall be implemented in accordance with the prevailing legislations.	with legislations on respective commodities. For GEP plants, the provision shall be Law No 12 of 1992 on Plant Cultivation System.
Part Three Use of GEP	
Article 24 The GEP as referred to in the Article 5 and has already been released as referred to in the Article 23 may be used for different needs in various areas in accordance with their respective license of use.	Article 25 Beside it's used for making food, animal feed, and industrial raw materials, GEP shall specifically be used for, among others: a. Animal GEP: as a hobby, sports, controlling of organism disturbing plants, media of science and technology, and as medicinal raw material; b. Fish GEP; as a hobby, sports, media of science and technology, crafts, and as ornament; c. GEP microorganism: as biological fertilizer, bio-remediation, biological pesticide, biological herbicide, pro-biotic, examination material for serology and animal biological activity, to produce antigen, antiserum, vaccine, and to process the production of bioactive organic compounds, and fine organic compounds; d. GEP plants: as biological fertilizer and bioremediation, ornamental plants, medicinal raw, and as the biological pesticide material.
CHAPTER VI SUPERVISION AND CONTROL OF GEP	

CONTENT	EXPLANATION
<p style="text-align: center;">Article 25</p> <p>The Minister, the competent Minister or the Head of competent LPND shall conduct supervision and control of the GEP on distribution and is used within the territory of Republic of in accordance with applicable legislation.</p>	<p>Article 26</p> <p>Supervision and control by the competent Minister or Head of competent LPND includes, among others, determination of personnel and or agency conducting the control, and the procedure of controlling and reporting in accordance with the applicable legislations in the relevant commodity area.</p>
<p style="text-align: center;">Article 26</p> <p>(1) The Minister, the competent Minister or the Head of competent LPND shall decide a guide to monitoring the impact and risk management of distributed GEP on the environment, while considering the input from BC.</p>	<p>Article 27</p> <p style="text-align: center;">Self-explanatory</p>
<p>(2) Monitoring as referred to in paragraph (1) shall be conducted by the Minsister, competent Minister or Head of competent LPND in accordance with the applicable legislations.</p>	

CONTENT	EXPLANATION
<p style="text-align: center;">Article 27</p> <p>(1) Any person who produces, imports from abroad and or distribute GEP which appears to create negative impact on the environment, human health and or animal health, shall report the accident to the Minister, competent Minister and or Head of competent LPND.</p>	<p>Article 28</p> <p>Paragraph (1)</p> <p style="padding-left: 40px;">Self-explanatory</p>
<p>(2) Any consumer or community knowing the release, distribution and or use of GEP, which appears to create negative impact on environment, human health and or animal health may report the case to the Minister, competent Minister and or Head of competent LPND.</p>	<p>Paragraph (2)</p> <p style="padding-left: 40px;">Self-explanatory</p>
<p>(3) The Minister, competent Minister and or Head of competent LPND, after receiving the report as referred to in the paragraph (10) and paragraph (2) shall assign BC to conduct inspection and prove the correctness of the report.</p>	<p>Paragraph (3)</p> <p style="padding-left: 40px;">Self-explanatory</p>
<p>(4) If the inspection result shows that the GEP so reported has caused negative impact on environment, human health and or animal health then:</p> <p style="padding-left: 20px;">a. The Minister shall suggest the competent Minister or Head of competent LPND to revoke the decision of release or distribution of the GEP.</p>	<p>Paragraph (4)</p> <p style="padding-left: 40px;">Self-explanatory</p>

CONTENT	EXPLANATION
b. The competent Minister or the Head of competent LPND shall then revoke the decision of release and distribution of GEP.	
(5) If the released GEP is found to create negative impact on environment, human health and or animal health then the responsible person shall conduct control as well as prevention and withdrawal of the related GEP from distribution.	Paragraph (5) Responsible person for activity shall mean anybody who produces, imports and or distributes GEP;
(6) Further regulation on GEP withdrawal shall be provided by the competent Minister or Head of competent LPND, based on input from BC;	Paragraph (6) Self-explanatory
(7) The reporting procedure as referred to in the paragraph 1 and paragraph 2 shall be in accordance with the applicable Legislations.	Paragraph (7) Self-explanatory
CHAPTER VII INSTITUTIONAL FRAMEWORK Section One Biosafety of Genetically Engineered Product Commission (BC)	
Article 28 BC shall assist the Minister, competent Minister and Head of competent LPND in giving recommendation about biosafety and in conducting control over importation and use of GEP, as well as inspection and proof of the correctness of the report about negative impact as mentioned in article 21, Article 26, and Article 27.	Article 29 Self-explanatory

CONTENT	EXPLANATION
<p style="text-align: center;">Article 29</p> <p>(1) Position, membership composition, main duties and function as well as authority of BC shall be determined further through Presidential Regulation at the proposal of the Minister.</p>	<p>Article 31</p> <p style="text-align: center;">Self-explanatory</p>
<p>(2) The Minister proposal as referred to in the paragraph 1 shall be made by taking note of suggestion and consideration of the competent Minister and/or Head of competent LPND.</p>	
<p style="text-align: center;">Article 30</p> <p>(1) Before an implemental regulation of this Government Regulation is provided, the Minister, Competent Minister or the Head of competent LPND shall, according to their respective areas, take note of suggestion and consideration of the BC.</p>	<p>Article 30</p> <p style="text-align: center;">Self-explanatory</p>
<p style="text-align: center;">SECTION TWO</p> <p style="text-align: center;">Biosafety Clearing House (IBCH)</p> <p style="text-align: center;">Article 31</p> <p>(1) IBCH is the part of BC in managing and providing information to the public.</p>	<p>Article 31</p> <p style="text-align: center;">Self-explanatory</p>
<p>(2) IBCH shall have the following duties:</p>	<p>Paragraph (2)</p>

CONTENT	EXPLANATION
<p>a. managing and providing information to public on the procedure, application acceptance, process and summary of assessment result;</p> <p>b. receiving input from the community and presenting result of assessment of the input.</p> <p>c. submitting information on formulation of recommendation to be submitted to the Minister, competent Minister or Head of competent LPND; and</p> <p>d. presenting to public the information about Decree of the Minister, competent Minister or Head of competent LPND about the assessed application.</p>	<p>Self-explanatory</p>
<p style="text-align: center;">Section Three</p> <p style="text-align: center;">Biosafety Technical Team (BTT)</p> <p style="text-align: center;">Article 32</p> <p>(1) BTT shall assist BC in conducting technical assessment on biosafety;</p>	<p>Article 32</p> <p>Self-explanatory</p>
<p>(2) Further regulation on the position, membership composition, main duties and function as well as authority of BTT shall be determined by Head of BC after taking into account the suggestion and consideration from the Minister, competent Minister and Head of competent LPND;</p> <p>(3) Membership of BTT as referred to in the paragraph (2) shall comprise a number of expertise from the various scientific disciplines related to GEP.</p>	<p>Paragraph (3)</p> <p>Membership of TTK consists of the expert because TTK</p>

CONTENT	EXPLANATION
	handles technical assessment which is scientific in nature which can only be handled by experts in their respective areas.
<p style="text-align: center;">CHAPTER VIII</p> <p style="text-align: center;">COST</p> <p style="text-align: center;">Article 33</p> <p>All costs needed to implement this government regulation shall be determined based on the legislations applicable in the area of the state finance.</p>	<p>Article 33</p> <p>Paragraph (1)</p> <p style="padding-left: 40px;">Self-explanatory</p>

<p style="text-align: center;">CHAPTER IX Transition regulation Article 34</p>	
<p>All application for release and/or distribution that has been submitted prior to the entry to the force of this regulation will be process following the available regulation</p>	
<p style="text-align: center;">Article 35</p>	
<p>In the case that accredited laboratories or limited facilities stipulated in article 20 (1) are not available, the competent Minister or Head of LPND can designate laboratories or facilities that comply minimum technical requirement according to this regulation</p>	
<p style="text-align: center;">CHAPTER X Final provision Article 36</p>	
<p>At the entry of force of this regulation, all other regulation related to the GE environmental safety, food safety and/or feed safety are still in force as long as it is not contradict with this decree or the item has not been further regulated by this government regulation.</p>	
<p style="text-align: center;">Article 37</p> <p>This Government Regulation is entry into force at the date this is published and legally binding. For the purpose of public information this will be published in Government Gazette.</p>	

Issued in: Jakarta

On : 19 May 2005

THE PRESIDENT OF THE
REPUBLIC OF INDONESIA

Signed by

Dr. H. SUSILO BAMBANG YUDHOYONO

Enacted in Jakarta

on 19 May 2005

Minister Of Law and Human Rights of
the Republic of Indonesia

Signed by

HAMID AWALUDDIN

STATE GAZETTE OF THE REPUBLIC OF INDONESIA OF 2005

NO 44 Tahun 2005