

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

Regulation signed by the President of RI in May 2005

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| <p style="text-align: center;">REGULATION OF THE GOVERNMENT OF THE REPUBLIC OF INDONESIA NUMBER 21 YEAR 2004</p> <p style="text-align: center;">ON</p> <p style="text-align: center;">BIOSAFETY OF GENETICALLY ENGINEERED PRODUCT</p> <p style="text-align: center;">With the Bless of God the Almighty</p> <p style="text-align: center;">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> <p>The use of biological diversity through modern biotechnology resulting in Genetically Engineered Product (PRG) has provided an opportunity to support agricultural production, food availability, and improvement of human</p> | |

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| | <p>life quality. Modern biotechnology used in producing PRG includes in-vitro Nucleate Acid and cell fusion. The Deoksiribose Nucleate 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 PRG 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 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</p> | |

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| | <p>existing legislations do not sufficiently regulate everything on PRG 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 PRG 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 PRG, research and development of PRG, importation of PRG from foreign country, assessment, release, and distribution and use of PRG, control of PRG, 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> <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 | |

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| | <p>Gazette of 1984, Number 22, Supplement to State Gazette Number 3274);</p> <p>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);</p> <p>d. Law Number 12 of 1992 on Plant Cultivation System (State Gazette of 1992, Number 46, Supplement to State Gazette Number 3478);</p> <p>e. Law Number 16 of 1992 on Animal, Fish, and Plant Quarantine (State Gazette of 1992, Number 56, Supplement to State Gazette Number 3482);</p> <p>f. Law Number 23 of 1992 on Health (State Gazette of 1992, Number 100, Supplement to State Gazette Number 3495);</p> <p>g. Law No. 5 of 1994 on Ratification of UN Convention on Biological Diversity);</p> <p>h. Law No. 7 of 1994 on Ratification of Agreement Establishing the WTO;</p> <p>i. Law Number 7 of 1996 on Food (State Gazette of 1996, Number 99, Supplement to State Gazette Number 3656);</p> <p>j. Law No., 8 on Consumers Protection.</p> | |

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| | <p>k. Law Number 41 of 1999 on Forestry (State Gazette of 1999, Number..., Supplement to State Gazette Number ...);</p> <p>l. Law number 29 of 2000 on Plant Variety Protection (State Gazette of 2000, Number 241, Supplement to State Gazette Number 4043);</p> <p>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);</p> <p>n. Law No. 18 of 2004 on Plantation;</p> <p>o. Law No. 21 of 2004 on Ratification of Cartagena Protocol;</p> <p>p. Law No. 31 of 2004 on Fishery;</p> <p>q. Law No.32 on Regional Development.</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 | | |

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| 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</p> <p style="text-align: center;">GENERAL PROVISION</p> | II. ARTICLE BY ARTICLE | |
| <p style="text-align: center;">Article 1</p> <p>Words used in this Government Regulation 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 style="text-align: center;">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</p> | | |

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| production, preparation, storage, distribution and use of food of genetically engineered product. | | |
| 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. | | |
| 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 product hereinafter referred as to PRG means a live 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 application of genetic engineering | | |

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| technique consisting of in-vitro Nucleate Acid and cell fusion of two or more types of organism outside taxonomical familiarity. | | |
| 9. PRG animal means animal resulted from genetically engineered technique application which greater or the whole part thereof lives on land. | | |
| 10. Material made from PRG animal means any material resulted from PRG animal that can be processed further for the need of human and other purpose. | | |
| 11. Product made from PRG animal means product made from material resulted from PRG animal which is processed with or without using additional material. | | |
| 12. PRG 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 PRG fish means any material resulted from PRG fish which can be further purchased for the human's and other purpose. | | |
| 14. Product made from PRG fish means product resulted from PRG fish material which is processed by certain way or method with or without using additional material. | | |

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| 15. PRG Plant means plant resulted from genetically engineered technique application. | | |
| 16. Material made from PRG plant means material resulted from PRG plant and can be further processed for human's or other purpose. | | |
| 17. Product of material resulted from PRG Plant means product originated in material resulted from PRG plant which can be processed with or without using additional material. | | |
| 18. PRG microorganism means microorganism resulted from genetically engineered technique application. | | |
| 19. Material made from PRG microorganism means body/cell of PRG microorganism and or its metabolism product. | | |
| 20. Product of material resulted from PRG microorganism means product resulted from material originated in body/cell of PRG microorganism or its metabolism product which processed by way or certain method with or without using additional material. | | |
| 21. Risk assessment of PRG means assessment of possible occurrence of influence that can affect environment, human health and animal health as a result of PRG development and use based on correct | | |

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| scientific method and certain statistic. | | |
| 22. Assessment means the whole process of document verification and test of PRG and related social and economic factor. | | |
| 23. Test means evaluation and technical assessment of PRG consisting of engineering technique, efficacy and requirement of biosafety in laboratory, limited test facility, and or limited test field. | | |
| 24. Biosafety Commission of Genetically Engineered Product hereinafter referred to as KKH means commission assigned to assist Minister in making and providing policy and issue PRG biosafety certificate. | | |
| 25. Biosafety Safety Clearing House of Genetically Engineered Product hereinafter referred to as BKKH means an element of KKH serving as communication facility between KKH and stakeholder. | | |
| 26. Biosafety Technical Team of Genetically Engineered Product hereinafter referred to as TTKH means team assigned to assist KKH in conducting evaluation and technical assessment of biosafety and PRG use feasibility. | | |
| 27. Notice means information delivery to the public on the result of the evaluation and technical assessment of PRG biosafety through KKH official news and notice board or mass media prior to | | |

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| granting of PRG biosafety recommendation by KKH. | | |
| 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 PRG. | | |
| 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 PRG. | | |
| 33. Head of Non-Departmental Agency hereinafter referred to as LPND means Head of LPND whose scope of duty covers distribution of PRG. | | |
| 34. Day means calendar days. | | |
| 35. Minister means Minister who is responsible for environment. | | |

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| <p style="text-align: center;">Article 2</p> <p>(1) The purpose of this Government Regulation is to realize environmental safety, food safety and or animal feed safety of PRG and its use in the area of agriculture, fishery, forestry, industry, environment and non pharmaceutical health.</p> | <p>Article 2</p> <p style="text-align: center;">Self-explanatory</p> | |
| <p>(2) The purpose of this government regulation is to improve efficiency and effectiveness of PRG 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>Arrangement applied in this government regulation is a precautionary approach in realizing 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, event 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 PRG 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 PRG on environment and human health shall be acceptable based on the existing requirement. Consideration in term of religion, ethic, socio</p> | |

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| | culture among others gen transformed into PRG coming from organism and does not violate any certain religious norms, shape or phenotype of PRG animal should equal to its older and be in line with prevailing esthetic. | |

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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 PRG; b. research and development of PRG; c. importation of PRG from abroad; d. assessment, release and distribution and use of PRG; e. supervision and control of PRG; 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 PRG</p> | | |
| <p style="text-align: center;">Section One</p> <p style="text-align: center;">Type of PRG</p> | | |
| <p style="text-align: center;">Article 5</p> <p>Type of PRG includes:</p> <ul style="list-style-type: none"> a. PRG animal, material resulted from PRG animal and its product; b. PRG fish, material resulted from PRG fish and its product; c. PRG plant, material resulted from PRG plant and its product; and d. PRG microorganism, material resulted from PRG 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 PRG</p> | | |
| <p style="text-align: center;">Article 6</p> | <p>Article 6</p> | |

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| (1) PRG be it originates from home or abroad, an assessment or test conducted for delivery or distribution 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 | Paragraph (1) Self-explanatory | |
| (2) The basic information as guide to fulfilling requirement of environmental safety as referred to in paragraph (1) shall include among others: a. Description and purpose of use; b. Change of genetics and phenotype expected to detect; c. Clear identity on taxonomy, physiology, and reproduction of PRG. d. Organism used as source of gen must clearly be stated. e. Genetically engineered method used shall comply with standard procedure which accuracy shall scientifically be justifiable. f. Molecular characteristic of PRG must be clearly stated g. Gen expression transformed into PRG must be stable. h. Applied manner of destruction in case of irregularity. | Paragraph 2 Letter a Self-explanatory Letter b Self-explanatory Letter c Self-explanatory Letter d Gen source shall clearly and completely be stated means that its origin in obtaining organism used as gen 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. Letter e Self-explanatory Letter f Must clear shall mean the assessment shall comply | |

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| | <p>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 procedure which accuracy shall scientifically be justifiable;</p> <p>b. PRG nutrient content shall substantially be equivalent to that of non-PRG.</p> <p>c. Hazardous compound, nutrient-resistant and allergic-inducing content in the PRG shall substantially be equivalent to that of non-PRG.</p> <p>d. Carbohydrate, protein, dust, fat, fiber, amino acid, fat acid and vitamin content in the PRG shall substantially be equivalent to that of non-PRG.</p> <p>e. Gen-coded protein removed shall not be allergen in nature.</p> <p>f. Way of destruction used in case of irregularities.</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> <p>Letter e Self-explanatory</p> | |

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

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| <p align="center">CHAPTER III</p> <p align="center">RESEARCH AND DEVELOPMENT OF PRG</p> | | |
| <p align="center">Article 8</p> <p>Any person conducting research and development of PRG shall prevent and or eradicate any negative impact on human and environment as a result of his activity.</p> | <p>Article 8</p> <p align="center">Self-explanatory</p> | |
| <p align="center">Article 9</p> <p>Test of PRG 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 align="center">Self-explanatory</p> | |
| <p align="center">Article 10</p> <p>PRG 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 PRG is correctly expressed.</p> | |
| <p align="center">Article 11</p> <p>(1) Government shall develop role and all components of community to conduct research and development in a bid to produce PRG at home.</p> | <p>Article 11</p> <p>Paragraph (1)</p> <p align="center">Self explanatory</p> | |
| <p>(2) In developing the role and the community as referred to in paragraph (1), the Government may give appreciation to the</p> | <p>Paragraph (2)</p> <p align="center">Self-explanatory</p> | |

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| community who can produce new PRG which is beneficial to the interest of the state. | | |
| (3) In the event that the community has yet to be able to play its role in conducting research and development of PRG, the Government shall conduct research and development in a bid to produce PRG. | Paragraph (3) Self-explanatory | |
| <p style="text-align: center;">Article 12</p> <p>1. PRG research and development 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 PRG 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 PRG FROM ABROAD | | |
| <p style="text-align: center;">Article 13</p> <p>(1) Any person who imports any PRG of the same type from abroad for the first time, shall submit an application to the competent Minister or Head of LPND</p> | Article 13 Paragraph (1) PRG of the same type means the same genetically engineered PRG including that of resulted from conventional crossbreeding. The same variety of different PRG result is not classified as the PRG of the same type. The PRG 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 PRG for the same | |

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| | <p>type shall no need be tested for its biosafety. Permit from the Minister shall only be required for the first time importation of PRG.</p> <p>The application as referred to in this paragraph shall also serve as notification from person who desires to import such PRG 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 PRG.</p> | |
| <p>(2) The application for importation of PRG shall, as referred to in the Article 6, be provided with document stating that the requirement of environmental safety, food safety, and or animal feed safety has been fulfilled.</p> | <p>Paragraph (2)</p> <p>Self-explanatory</p> | |
| <p>(3) In addition to fulfilling the requirement as referred to in the paragraph (2), the importation of PRG from abroad shall also be provided with:</p> <ul style="list-style-type: none"> a. Certificate of free trade stating that the PRG 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),</p> | <p>Paragraph (4)</p> | |

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| <p>the competent Minister or the Head of LPND shall then:</p> <p>a. check for the full set of document and fulfilling of requirement as referred to in the paragraph (2) and paragraph (3);</p> <p>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 PRG.</p> | <p>In addition to the full set of certificate stating that the PRG has been in the free trade in its country of origin and assessment document and risk management, the importation of PRG from 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 LPND shall request an environmental safety recommendation with the Minister.</p> | <p>Paragraph (5)</p> <p>Self-explanatory</p> | |
| <p>(6) The competent Minister or the Head of LPND shall use the biosafety recommendation issued by the Minister of the Head of KKH as basis for his decision.</p> | <p>Paragraph (6)</p> <ul style="list-style-type: none"> ▪ For variety release, the Competent Minister is Minister of Agriculture; ▪ For fish release: Min of Marine and Fisheries; ▪ For forest trees: Minister of Forestry; ▪ For processed food release: Head of Food and Drug Control Agency (BPOM) | |
| <p>(7) The provision on the requirement and procedure for importation of PRG from abroad shall further be provided by the competent Minister of the Head of LPND.</p> | <p>Paragraph (7)</p> <p>Basic provision on requirement and procedure for importation of PRG from abroad issued by the Minister shall inter alia include the compliance with regulation in</p> | |

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| | the area of quarantine. | |
| <p style="text-align: center;">CHAPTER V ASSESSMENT, RELEASE AND DISTRIBUTION, AS WELL AS USE OF PRG Section One Assessment Procedure</p> | | |
| <p style="text-align: center;">Article 14</p> <p>(1) Assessment of PRG 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 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 LPND shall, within no later than 14 days, submit application for recommendation of biosafety to the Minister or Head of KKH.</p> | | |

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| <p style="text-align: center;">Article 15</p> <p>(1) In providing recommendation of biosafety of PRG as referred to in Article 14 paragraph (3), the Minister, competent Minister or the Head of LPND shall assign KKH 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, KKH shall, if deemed necessary, assign TTKH to conduct assessment of technical document and advanced test.</p> | <p>Article 15</p> <p>Paragraph (1) Self-explanatory</p> <p>Paragraph (2) Self-explanatory</p> <p>Paragraph (3) Period for conducting advanced test at laboratory, limited test facility (greenhouse, cage, pool) and limited test field shall be based on the type and nature of the PRG being assessed.</p> | |
| <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 KKH.</p> <p>(5) Result of technical evaluation and assessment of PRG Biosafety conducted by TTKH shall, within no later than 7 days after completion of the technical evaluation and assessment, be delivered to KKH as material for proposing recommendation of PRG biosafety.</p> | <p>Paragraph (4) Self-explanatory</p> <p>Paragraph (5) Self-explanatory</p> | |

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| <p style="text-align: center;">Article 16</p> <p>(1) The result of the technical evaluation and assessment submitted to KKH as referred to in the Article 15 paragraph (5) shall, within no later than 15 (fifteen) days, announce the receipt of the application, process and summarize the result of the assessment at a place 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 in the paragraph (1), no community gives response thereto, the community shall be deemed to have no objection to the proposed recommendation from KKH.</p> <p>(4) Upon completion of the period of the announcement as referred to in the paragraph (1), BKKH shall, within no later than 7 days, submit report on community response to KKH.</p> <p>(5) KKH shall, within no later than 14 days as of receipt of the report from BKKH, submit the proposed recommendation of environmental safety and or animal feed safety to the competent Minister or Chairman of LPND.</p> | | |

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| <p style="text-align: center;">Article 17</p> <p>(1) In serving PRG Biosafety recommendation to the competent Minister or competent Head of LPND, the Minister or Head of KKH shall take notice of the recommendation proposed by KKH and input from the community.</p> <p>(2) In the event that the said PRG 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 KKH, serve the environmental safety recommendation to the competent Minister or the competent Head of 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 ecology; | | |

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| <p>ii. explanation on PRG 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 PRG 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 KKH to make a conclusion to grant a recommendation on environmental safety and or food safety and or animal feed safety of PRG.</p> | |
| <p>(2) The applicant shall conduct food safety test at laboratory for PRG 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 PRG which application is submitted for first time distribution.</p> | <p>Paragraph (2)</p> <p style="padding-left: 40px;">Self-explanatory</p> <p>Paragraph (3)</p> <p style="padding-left: 40px;">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 PRG; 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 PRG 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 competent Head of LPND according to their main duties and functions.</p> | <p>Paragraph (4)</p> <p>Self-explanatory</p> | |

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| <p style="text-align: center;">Article 21</p> <p>(1) KKH shall assign BKKH to publicize the summary of the result of PRG assessment conducted by TTKH through mass media both printed and electronic in addition to official news by KKH for 60 days as of receipt of the technical assessment from TTKH.</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 PRG. With such a publication, the community can get opportunity to give its response in writing to KKH. Publication shall be carried out by inserting it in any publication media provided by KKH or through BKKH 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 KKH.</p> <p>(3) Response from the community as referred to in the paragraph (2) served to KKH 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 TTKH's assessment and input from the community, KKH shall propose its recommendation on:</p> <ul style="list-style-type: none"> a. safety condition of PRG environment to the Minister; b. safety condition of PRG food and or animal feed to the competent Minister and or competent Head of LPND. | <p>Paragraph (2)</p> <p style="padding-left: 40px;">Self-explanatory</p> <p>Paragraph (3)</p> <p style="padding-left: 40px;">Self-explanatory</p> <p>Paragraph (4)</p> <p style="padding-left: 40px;">Self-explanatory</p> | |
| <p>(5) PRG which passed assessment test shall be provided with a</p> | <p>Paragraph (5)</p> | |

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| <p>certificate of test result of environmental safety, food safety, and or animal feed safety by KKH 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, KKH shall serve to the Minister, the material for biosafety recommendation.</p> | |
| <p>(6) In case of failure in the assessment test, KKH 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 Basic rules on the procedure of PRG safety test includes, among others, procedure on application for test of biosafety and or food safety and or animal feed safety of PRG, procedure for conducting the test, making of recommendation, and period of assessment.</p> | |

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| <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 competent Head of LPND, provided with certificate of environmental safety;</p> <p>b. KKH shall submit the recommendation of food safety and or PRG food safety to the competent Minister or competent Head of LPND, provided with certificate of food safety and or animal feed safety of PRG;</p> <p>(2) Competent Minister or Competent Head of 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 PRG, in accordance with applicable legislations.</p> | <p>Article 23</p> <p>Self-explanatory</p> | |

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| <p style="text-align: center;">Section Two</p> <p style="text-align: center;">Release and Distribution of PRG</p> <p style="text-align: center;">Article 23</p> <p>For PRG which has already received its recommendation of biosafety, the decision for its release and or distribution shall be implemented in accordance with the prevailing legislations.</p> | <p>Article 24</p> <p>The decision for release and or distribution of PRG shall comply with legislations on respective commodities. For PRG plants, the provision shall be Law No 12 of 1992 on Plant Cultivation System.</p> | |
| <p style="text-align: center;">Part Three</p> <p style="text-align: center;">Use of PRG</p> | | |
| <p style="text-align: center;">Article 24</p> <p>The PRG 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.</p> | <p>Article 25</p> <p>Beside it's used for making food, animal feed, and industrial raw materials, PRG shall specifically be used for, among others:</p> <p>a. Animal PRG: as a hobby, sports, controlling of organism disturbing plants, media of science and technology, and as medicinal raw material; b. Fish PRG; as a hobby, sports, media of science and technology, crafts, and as ornament; c. PRG 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. PRG plants: as biological fertilizer and bioremediation,</p> | |

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| | ornamental plants, medicinal raw, and as the biological pesticide material. | |
| <p style="text-align: center;">CHAPTER VI</p> <p style="text-align: center;">SUPERVISION AND CONTROL OF PRG</p> <p style="text-align: center;">Article 25</p> <p>The Minister, the competent Minister or the competent Head of LPND shall conduct supervision and control of the PRG 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 competent Head of 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 competent Head of LPND shall decide a guide to monitoring the impact and risk management of distributed PRG on the environment, while considering the input from KKH.</p> | <p>Article 27</p> <p>Self-explanatory</p> | |
| <p>(2) Monitoring as referred to in paragraph (1) shall be conducted by the Minsister, competent Minister or competent Head of LPND in accordance with the applicable legislations.</p> | | |

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| <p style="text-align: center;">Article 27</p> <p>(1) Any person who produces, imports from abroad and or distribute PRG 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 competent Head of 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 PRG, 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 competent Head of LPND.</p> | <p>Paragraph (2)</p> <p style="padding-left: 40px;">Self-explanatory</p> | |
| <p>(3) The Minister, competent Minister and or competent Head of LPND, after receiving the report as referred to in the paragraph (10) and paragraph (2) shall assign KKH 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 PRG 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 competent Head of LPND to revoke the decision of release or distribution of the PRG.</p> <p style="padding-left: 20px;">b. The competent Minister or the competent Head of LPND shall</p> | <p>Paragraph (4)</p> <p style="padding-left: 40px;">Self-explanatory</p> | |

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| then revoke the decision of release and distribution of PRG. | | |
| (5) If the released PRG 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 PRG from distribution. | Paragraph (5) Responsible person for activity shall mean anybody who produces, imports and or distributes PRG; | |
| (6) Further regulation on PRG withdrawal shall be provided by the competent Minister or competent head of LPND, based on input from KKH; | 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 (KKH) | | |
| Article 28 KKH shall assist the Minister, competent Minister and competent Head of LPND in giving recommendation about biosafety and in conducting control over importation and use of PRG, 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 | |

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| <p style="text-align: center;">Article 29</p> <p>(1) Position, membership composition, main duties and function as well as authority of KKH 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 competent Head of 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 competent Head of LPND shall, according to their respective areas, take note of suggestion and consideration of the KKH.</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 (BKKH)</p> <p style="text-align: center;">Article 31</p> <p>(1) BKKH is the part of KKH in managing and providing information to the public.</p> | <p>Article 31</p> <p style="text-align: center;">Self-explanatory</p> | |
| <p>(2) BKKH shall have the following duties:</p> <p style="padding-left: 20px;">a. managing and providing information to public on the</p> | <p>Paragraph (2)</p> <p style="text-align: center;">Self-explanatory</p> | |

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| <p>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 competent Head of LPND; and</p> <p>d. presenting to public the information about Decree of the Minister, competent Minister or competent Head of LPND about the assessed application.</p> | | |
| <p style="text-align: center;">Section Three</p> <p style="text-align: center;">Biosafety Technical Team (TTKH)</p> <p style="text-align: center;">Article 32</p> <p>(1) TTKH shall assist KKH 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 TTKH shall be determined by Head of KKH after taking into account the suggestion and consideration from the Minister, competent Minister and competent Head of LPND;</p> <p>(3) Membership of TTKH as referred to in the paragraph (2) shall comprise a number of expertise from the various scientific disciplines related to PRG.</p> | <p>Paragraph (3)</p> <p>Membership of TTK consists of the expert because TTK handles technical assessment which is scientific in nature</p> | |

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| | 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> | |

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| <p>Issued in: Jakarta On : 19 May 2005 THE PRESIDENT OF THE REPUBLIC OF INDONESIA</p> <p>Signed by</p> <p>Dr. H. SUSILO BAMBANG YUDHOYONO</p> <p>Enacted in Jakarta on 19 May 2005 Minister Of Law and Human Rights of the Republic of Indonesia Signed by HAMID AWALUDDIN</p> <p>STATE GAZETTE OF THE REPUBLIC OF INDONESIA OF 2005 NO 44 Tahun 2005</p> | <p>SUPPLEMENT TO STATE GAZETTE OF THE REPUBLIC OF INDONESIA OF 2004 NUMBER</p> | |
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