NATIONAL BIOSAFETY FRAMEWORK OF THE REPUBLIC OF INDONESIA

Ministry of Environment of the Republic of Indonesia
Cooperating with
UNEP-GEF Project for the Development of
National Biosafety Framework in Indonesia
2004

Disclaimer

EXECUTIVE SUMMARY

In the last two decades, Indonesia has engaged in capacity building to welcome the development of biotechnology and since 1993 started to do research and development in agricultural biotechnology. Indonesia believes in the potential of modern biotechnology and genetic engineering for food production, medicine development and human health, therefore the country wants to embrace and use the technology. On the other hand, Indonesia has been aware of the controversy about the safety aspects of modern biotechnology, and chooses to take the precautionary approach to avoid the potential adverse impacts on food safety and the environment. In May 2000, Indonesia signed the Cartagena Protocol and on July 17, 2004 the Indonesian House of Representatives agreed upon the proposal from the Government of Indonesia to ratify the Protocol. On October 19th, 2004, the President of the Republic of Indonesia signed Law no 21, 2004 on Ratification of Cartagena Protocol.

Before the ratification of the Cartagena Protocol, Indonesia already developed measures to prevent adverse effects of Living Modified Organisms (LMOs), first in the form of The Decree of the Minister of Agriculture No 856 Kpts/Hk.330/9/1997 on the Provision of Biosafety of Genetically Engineered Agricultural Biotechnology Products which was later revised with the Joint Decree of Four Ministers (Minister of Agriculture, Minister of Forestry and Estate Crops, Minister of Health and State Minister for Food and Horticulture No 998.1/Kpts/OT.210/9/99 790.a/Kpts-IX/19991145A/MENKES/SKB/IX/1999 015A/NmenegPHOR/09/1999) on Biosafety and Food Safety of Genetically Engineered Agricultural Products in 1999. However, this regulation has to be updated due to a change in the composition of ministries, the need to include the Ministry of Environment as a focal point of the Cartagena Protocol, and to comply with the Cartagena Protocol.

In order to implement the Cartagena Protocol, the State Ministry of Environment of Indonesia proposed for assistance from the United Nation Environment Program, Global Environment Facility (UNEP-GEF), for a project for the Development of a National Biosafety Framework for Indonesia.

The objective of this UNEP/GEF Project is to prepare Indonesia for the entry into force of the Protocol, by, among others, assisting in the following activities:

1. Carrying out an assessment of the current technological capacity to manage Biosafety issues, and the implications of this on the implementation of a National Biosafety Framework;
2. Strengthening national capacity to develop national regulatory biosafety frameworks;
3. Strengthening national capacity for competent decision making on notifications and requests related to Living Modified Organisms (LMOs), including the establishment of appropriate administrative systems;
4. Support regional and sub-regional collaboration, including harmonisation of the implementation of national regulations;
5. Raise public awareness and improve information flow to the public on the issues involved in the release of Living Modified Organisms to promote informed debate and to ensure transparency with respect to the regulation of LMOs.
6. Provide all stakeholders with an opportunity to be involved in the design and implementation of a National Biosafety Framework.

The project started with surveys to study the existing conditions of biosafety in Indonesia, a series of workshops to advocate the concept of the Cartagena Protocol and to get input from stakeholders, training courses for biosafety assessors, decision makers as well as other stakeholders, for instance high school teachers and members of the House of Representatives. Moreover, a Guideline for the Biosafety Assessment of Genetically Engineered Products has also been reviewed and updated. Through this project, a Biosafety Clearing House has been established with the following duties: to maintain and serve information to the public about procedures, acceptance of proposals, process and summary of result assessments; to receive inputs from the public, to asses the input and submit it to the Committee,

and to provide information for the draft of the recommendation from the Biosafety Committee which will be submitted to the related Minister and/or Non-Departmental Government Institutions; and providing information about the decision of the related Minister or Non-Departmental Government Institutions about the proposals.

At the end of the project a working document presenting a framework for implementing a national biosafety system was developed covering the following elements:

- national policies regarding biosafety and related aspects
- regulatory regime
- systems to handle notifications or requests for authorization
- monitoring and enforcement
- public awareness, education and participation

In its concluding remarks the document highlights the need to raise public awareness and education and to strengthen the national capacity to implement the national biosafety system at the individual, institutional, and system-wide levels.

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FOREWORD

In order to use biotechnology and at the same time safeguard the environment, biodiversity and human health, Indonesia signed the Cartagena Protocol on May 24th, 2000. In 2002, the Ministry of Environment together with other stakeholders, mainly the Indonesian Agency for Agricultural Research and Development, the Department of Agriculture and the Indonesian Institute of Sciences, jointly worked to build the National Biosafety Framework for Indonesia. The Framework development is supported by a UNEP-GEF Project intended to help developing countries to cope with the biosafety and food safety aspects of LMOs.

The end of the project has been marked by the development of the National Biosafety Framework, the Draft of the Government Regulation for Biosafety and Food Safety of Genetically Engineered Products, the Guidelines for Risk Assessment and Risk Management of LMOs, and the Biosafety Clearing House for data exchange and public participation purposes. On July 17th, 2004, the House of Representatives of the Republic of Indonesia agreed upon the proposal of the Government to ratify the Cartagena Protocol, and the Cartagena Protocol was officially ratified at October 19th, 2004 by Law No 21, 2004.

Although the framework is developed, more work needs to be done to implement the Protocol. However, the results of the present project will serve as a concrete base to move forward. The achievement of the project is the fruit of the hard work of everybody involved. I would like to thank especially the National Coordinating Committee Members, and experts from the various institutions supervising, guiding and advising the Project.

To all of the stakeholders assisting the Ministry of Environment, especially colleagues from the Department of Agriculture, the Indonesian Institutes of Sciences, the National Agency for Drug and Food Control, Bogor Agriculture University, Gadjah Mada University, University of Indonesia, on behalf of the Ministry I express my gratitude and hope for better cooperation in the future.

To UNEP-GEF I also express my gratefulness for the financial and capacity building assistance in establishing the National Biosafety Framework for Indonesia.

Jakarta, 20 Oktober 2004

Sudariyono
Deputy for Environmental Conservation
Ministry of Environment
Republic of Indonesia

GLOSSARY

AFTA	:	ASEAN FREE TRADE AREA
ASEAN	:	Association of South East Asian Nations
AMAF	:	ASEAN Ministers of Agriculture and Forestry
ASOEN	:	ASEAN Senior Officials on Environment
BCH	:	Biosafety Clearing House
BC	:	Biosafety Committee
BFSC	:	Biosafety and Food Safety Committee (Komisi Keamanan Hayati dan Keamanan Pangan or abbreviated as KKHKP)
BFSTT	:	Biosafety and Food Safety Technical Team (Tim Teknis Keamanan Hayati dan Keamanan Pangan or abbreviated as TTKHKP)
BTT	:	Biosafety Technical Team
Bt	:	*Bacillus thuringiensis*
CBD	:	Convention on Biological Diversity
COP	:	Conference of the Parties
COST	:	ASEAN Committee on Science and Technology
DG	:	Director General
GEABP	:	Genetically Engineered Agricultural Biotechnology Product
GEAP	:	Genetically Engineered Agricultural Products
GEF	:	Global Environment Facility
GEP	:	Genetically Engineered Product (Produk Rekayasa Genetik or abbreviated as PRG)
GM Food	:	Genetically Modified Food
GMAC	:	Genetic Modification Advisory Committee
GMO	:	Genetically Modified Organism
GR	:	Government Regulation
IAARD	:	Indonesian Agency of Agriculture Research and Development
ICABIOGRAD	:	Indonesian Center for Agricultural Biotechnology and Genetic Resources Research and Development (Balai Besar Penelitian dan Pengembangan Bioteknologi dan Sumber Daya Genetik or abbreviated as BB-BIOGEN)

IIS	: Indonesian Institute of Sciences (Lembaga Ilmu Pengetahuan Indonesia or abbreviated as LIPI)
LMO	: Living Modified Organism
MOP	: Meeting of the Parties
NADFC	: National Agency for Drug and Food Control
NAGM	: National Authority on Genetic Modification
NBF	: National Biosafety Framework
NCC	: National Coordinating Committee
NEA	: National Executing Agency
NGOs	: Non Governmental Organizations
RCB-IIS	: Research Center for Biotechnology, Indonesian Institute of Sciences (Pusat Penelitian Bioteknologi LIPI)
UNEP	: United Nation Environmental Program

INFORMATION ON THE PROJECT DEVELOPMENT

Indonesia joined the UNEP/GEF Project “Development of the National Biosafety Framework” on September 1, 2002, with a predicted duration of 18 months.

The National Coordinating Committee (NCC) was established, consisting of 16 members, experts of biosafety from related institutions, non-governmental organisations and the private sector. Dr Tantono Subagyo, of the Indonesian Intellectual Property Society, was nominated as the National Project Coordinator. The National Executing Agency was the Ministry of Environment, the contact person formerly was Dra. Liana Bratasida, MSc, (chmcbdri@rad.net.id) Deputy of Environmental Conservation and later due to the tour of duty was replaced by Ir. Utami Andayani MSi (utamikun@yahoo.com) . Details of the project organization and members of the NCC are presented in Annex I.

Indonesia signed the Cartagena Protocol on Biosafety when it was open for signature for the first time on May 24, 2000, during the fifth meeting of the Conference of the Parties to the Convention on Biological Diversity in Nairobi, Kenya.

In the beginning of the project, surveys were conducted to learn more about the “state of the art” of biotechnology and biosafety in Indonesia, i.e.

1. Survey of existing uses of biotechnology and the arrangements for safe use of biotechnology, including review and assessment of existing legislation that may impact the use of modern biotechnology.
2. Survey on existing national, bilateral and multilateral co-operative programs in capacity building, R & D and application of biotechnology;
3. Survey on the extent and impact of the release of LMOs and commercial products in Indonesia;
4. Survey on existing national biosafety frameworks in countries of the sub-region;
5. Survey on existing mechanisms for harmonization of risk assessment/risk management, mutual acceptance of data and data validation.

The surveys give an idea about the recent condition of biotechnology in Indonesia and the gaps that need to be filled before a strong biosafety system can be established.

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Several workshops were organized for different groups of stakeholders such as students, university lecturers, and members of the House of Representatives from the Environmental Caucus to promote the Cartagena Protocol and the National Biosafety Framework for Indonesia. Moreover, the Biosafety Clearing House for Indonesia was also established with the website: www.bchindonesia.org, aimed as the primary tool for public communication and participation (26). Training was performed for various stakeholders, namely: public awareness on biotechnology and biosafety for High School Teachers, and risk assessment and risk management of genetically engineered products for decision makers and assessors. Lastly, the project succeeded in facilitating the updating of the Guideline for the Assessment of Environmental Risk for Genetically Engineered Products in four series i.e : General Guideline, Guideline for Plants, Guideline for Food and Guideline for Feed. These guidelines can be used as tools for assessment in the existing regulatory regime and will be improved and updated after the declaration of the related Government Regulation.

The Report on the Project is structured into 7 main chapters:

1. Introduction, consisting of the state of the art of biotechnology research in Indonesia, and utilization of genetically engineered products.
2. Description of the national policy on biotechnology and biosafety in relation to Environmental Policy, Agricultural Policy, and Health and Food Policy.
3. Description of the regulatory regime, ministerial decree related to biosafety in force and institutions responsible for their implementation. Information on future systems, mainly the Draft of the Government Regulation for Biosafety and Food Safety.
4. System to handle notifications or requests for authorization of certain activities, and its National Competent Authorities.

5. Monitoring of impacts on the environment and human health, responsible institutions, and enforcement.
6. System and measures to enhance public education, awareness and participation, basic information on the Biosafety Clearing House, and related websites. Future goals and mechanisms to achieve them.
7. Concluding Remarks

I. INTRODUCTION

The rapid progress in biotechnology, especially in modern biotechnology and genetic engineering, enables people to produce new varieties containing desirable traits from various unrelated organisms, which was formerly impossible using traditional breeding methods.

In the Cartagena Protocol, the products of modern biotechnology are called living modified organisms (LMOs), while the general public uses the term: genetically modified organisms (GMOs). In Indonesia, since 1997, these products were referred to as Genetically Engineered Agricultural Biotechnology Products (GEABPs), later changed to Genetically Engineered Agricultural Products (GEAPs), and changed further to Genetically Engineered Products (GEPs). In this report, the appropriate term will be used according to the context.

Rightly applied, applications of modern biotechnology in agriculture have a real potency to contribute to increasing agriculture productivity, decreasing poverty and increasing food security. However, there are different perceptions regarding the impact of modern biotechnology, especially concerning long term effects to the environment, biodiversity and human health.

The prospects of modern biotechnology and the difference in perceptions for the safety of the product have induced the development of a regulation regime specifically for the assessment of LMOs. Internationally, the Convention on Biological Diversity (CBD) addresses this problem, and after many lengthy discussions, on January 29, 2000 in Montreal Canada the CBD opened the "Cartagena Protocol on Biosafety to the Convention on Biological Diversity" (hereafter called the "Cartagena Protocol") for members signatory. The Cartagena Protocol is the Protocol for regulating safe transfer, handling and utilization of LMOs. The objective of the protocol is to ensure a high level of protection regarding the safe transfer, handling and utilization of LMOs resulting from modern biotechnology which may potentially have harmful effects on the conservation and sustainable utilization of biodiversity, with a special emphasis on human health and a specific concern with transboundary movement (25). By June 4th, 2001 the Protocol was signed by 103 countries and by May 24th, 2004

ratified by 100 countries. The Protocol entered into force on September 11th, 2003, 90 days after the 50th ratification, and the Conference of the Parties and Meeting of the Parties (COP-MOP) were held in Malaysia after the 7th COP of CBD from February 23rd to 27th, 2004.

With an awareness of the importance of modern biotechnology, Indonesia has been developing a regulatory system for the biosafety of GEABPs since 1997 with The Decree of the Minister of Agriculture No 856 Kpts/Hk.330/9/1997 on the Provision of Biosafety of Genetically Engineered Agricultural Biotechnology Products, which was later revised with the Joint Decree of Four Ministers (Minister of Agriculture, Minister of Forestry and Estate Crops, Minister of Health, and State Minister for Food and Horticulture No 998.1/Kpts/OT.210 /9/99 790.a/Kpts- IX/19991145A/MENKES/ SKB/IX/1999 015A/NmenegPHOR/09/ 1999) on Biosafety and Food Safety of Genetically Engineered Agricultural Products (24). On May 24th, 2000, Indonesia signed the Cartagena Protocol, and on July 17th, 2004, the House of Representatives agreed upon Government requests to ratify the Cartagena Protocol. On Octoner 19th, 2004, the Republic of Indonesia officially ratify Cartagena Protocol with Law No 21, 2004.

The biotechnology and biosafety situation in Indonesia

To give an overview of the current biotechnology and biosafety situation in Indonesia, several surveys have been performed under the auspices of the project, collaborating with the Indonesian Center for Agricultural Biotechnology and Genetic Resources Research and Development (ICABIOGRAD), Department of Agriculture or in Indonesia known as BB-BIOGEN, and the Research Centre for Biotechnology, Indonesian Institute of Sciences (RCB-IIS) also known as Pusat Penelitian Bioteknologi, Lembaga Ilmu Pengetahuan Indonesia (LIPI).

Interest in biotechnology in Indonesia started as early as 1985 with the establishment of a National Committee for Biotechnology by the State Ministry for Research and Technology. The main objective was to prepare and formulate

policies and programs for the national development of biotechnology including priority setting and funding, coordination of research activities, and to provide guidance for human resource development, intellectual property rights, release of genetically engineered organisms, and enhanced involvement of the private sector in biotechnology research and development (1).

The majority of institutions dealing with biotechnology and biosafety are governmental institutions. They include the so called "non-department governmental institutions" (non-department governmental institutions, or in Indonesian: Lembaga Pemerintah Non Departemen, are government institutions outside any specific department, for instance: The Indonesian Institute of Science, the National Agency for Drug and Food Control, and the National Atomic Energy Agency) under the coordination of the State Ministry for Research and Technology, research centers of the Ministry of Agriculture, and public universities. Research institutions coordinated by the State Ministry for Research and Technology include the Indonesian Institute of Sciences (LIPI) and the Agency for the Assessment and Application of Technology (BPPT). They have been assigned to undertake research and development in industrial, medical, and agricultural biotechnology. Research institutes under the Department of Agriculture have a more specific task to conduct research and development in biotechnology to help improve food and plantation crops as well as animal production. Furthermore, institutions under the universities are responsible with human resource development as well as basic research in biotechnology. At that time, there were three centers of excellence with such responsibilities, i.e. the Inter-University Center (IUC) for Agricultural Biotechnology of Bogor Agricultural University, the Inter-University Center for Industrial Biotechnology of the Bandung Institute of Technology, and the Inter-University Center for Medical Biotechnology of Gajah Mada University (1). Later, the IUCs at each University were transformed into Centers for Biotechnology Study.

During the period from 1989-1997, there were 3 research institutes actively conducting research on modern agriculture biotechnology: the Research Center for Food Crops Biotechnology of the Department of Agriculture (RIFCB)

later renamed ICABIOGRAD, the Research Center for Biotechnology under the Indonesian Institutes of Science (RCB-IIS), and the Inter-University Center for Agricultural Biotechnology at Bogor Agricultural University. They absorbed a high proportion (around 60%) of researchers, and about 70% of total expenditures of the available resources in that field. During that time, research expenditures grew almost triple than that of research personnel. Since then many of the scientists have become more familiar with genetic engineering techniques. This is reflected in the increased number of personnel and disciplines associated with “modern" biotechnology being studied, as well as the increased number of research centers involved in research activities on modern biotechnology and biosafety (1).

Due to the economic crisis in 1998-2002/03, there was a significant reduction (as much as 30%) in the number of research personnel and the amount of research funding. In spite of this, there was an increase in the number of both public and private research institutes involved in biotechnology and biosafety. While in 1997 research activities on plant genetic engineering were conducted only in a limited number of public research institutes, in 2002 such activities were conducted not only in public research institutes but also in several private companies and universities. This research now includes a variety of different traits being modified in a number of different commodities (1, 24).

In 2002/03, the total number of personnel working in the area of biotechnology and biosafety in public research institutions is 205, with 71 PhDs, and 49 Masters-level scientists. As could be expected, the number of personnel in non-public research institutions such as private companies, NGOs and universities, was less than in public research institutions (1).

From the 55 institutions surveyed in Indonesia, most of them are equipped for working on tissue culture, molecular biology, microbiology and fermentation. Most of the reseach employs conventional biotechnology, only 12 institutions are conducting research in modern biotechnology. Among them, only 6 institutes have a gene gun (1).

A number of public and non-public research institutions, universities, and private companies are still actively conducting research on genetic engineering of various plant commodities, such as rice, soybean, peanut, sweet potato, cabbage, cacao, sugar cane, papaya, palm oil, citrus, eucalyptus, *albizia* (sengon), and teak. Among the institutes in Indonesia, there are two institutions, namely RCB-IIS and ICABIOGRAD, equipped with a contained greenhouse with an international-standard biosafety facility. These facilities are being used by the Technical Team for Biosafety and Food Safety to conduct biosafety tests of transgenic organisms.

The research projects performed in Indonesia are mainly in product development, and only a few on biosafety. Several research projects have been done in biosafety, in conjunction with product registrations; however, capacity building for biosafety is badly needed. Research performed in Indonesia and the institutions involved are presented in Annex II.

In terms of direct utilization as food, feed and processing (Ffps), in 2002 Indonesia imported 1,153,063 metric tons of maize and 1,365,253 metric tons of soybean (27). Most of the soybean and maize are imported from USA, Brazil and Argentina, therefore it is safe to assume that the importations contain a fair amount of GMOs (2).

In 1998 Monsanto submitted a proposal to the Government of Indonesia to release Bt cotton (DP 5690 B) or widely known with its trademark Bollgard (2). It was tested and judged to be safe for the environment, and in 2001 released temporarily (the permit have to be renewed every year) in 7 districts and later in 2003 extended to 9 districts in Sulawesi. However, due to the controversy between stakeholders and the inadequacy in the regulation, Monsanto withdrew Bt cotton in 2002 (2). Meanwhile, several transgenic organisms such as corn, cotton and enzyme for feed are already in the pipeline, already being tested or still to undergo testing (Annex III).

The reality that Indonesia uses a lot of LMOs and in the long run will also develop LMO products stresses the importance of building strong and workable biosafety frameworks in the country. Therefore, the ratification of the Cartagena

Protocol and the development of the National Biosafety Framework are very timely, although in order to implement it, the Government has to initiate a capacity building program.

II. BIOSAFETY POLICY

Indonesia is a nation populated by 217,131 million people in 2002 (27), with 18,306 islands (28), located in the equatorial belt and comprising one of the world's centers of megadiversity. Indonesia is very concerned with the conservation and sustainable use of biodiversity. On the other hand, due to the struggle in providing food for its large population, Indonesia is also extremely concerned with food security. As a developing nation, Indonesia also prioritizes science and technology for maximum benefit, while minimizing the negative impact of the technology.

The policy for biosafety in Indonesia was first established in 1997 in the form of the decree of the Minister of Agriculture No. 85/Kpts/HK.330/9/1997 on the Provisions on Biosafety of Genetically Engineered Agricultural Biotechnology Products(4). This Decree was established because of the absence of policy directly related with biosafety in agriculture. In 1999, in order to include food safety aspects the decree was revised to become a Joint Decree of Four Ministers (Minister of Agriculture, Minister of Forestry and Estate Crop, Minister of Health, and State Minister of Food and Horticulture) on Biosafety and Food Safety of Genetically Engineered Agricultural Products. No: 998.1/Kpts/OT.210/9/99; 790.a/Kpts-IX/1999; 1145A/MENKES/SKB/IX/1999; 015A/ NmenegPHOR/09/1999 (24). So far, this Joint Ministerial Decree has been utilized to implement biosafety policy in Indonesia. There are needs to improve the policy and to develop a new regulation as the Government Regulation on Biosafety of Genetically Engineered Products.

The abovementioned policy is part of the nation's policy on people's welfare, encompassing environment, food, health, agriculture, science and technology, and national development programs as described below.

Policy on Environment

In the article 5 and 6 of the Law on Environment (19) the right of every person to have a healthy environment and the responsibility of the government to conserve and maintain the function of the environment and to prevent and

mitigate pollution and destruction of the environment was emphasized. In article 7, there is a special section stating that every person has a right to be informed about their environment and every person doing activities has to give accurate and true information about the management of the environment related to the said activities. It is emphasized as well that people have an equal and unlimited opportunity to take a role in the management of the environment.

Article 9.3 of the Law on Environment stated further that the management of environment has to be done with an integration of area distribution, conservation of non-biological resources, conservation of man made resources, conservation of biological resources and its ecosystem, and conservation of culture, biodiversity and climatic changes. Furthermore, in article 18 and 19, it is stressed that all of the work plan and/or activities which may have a signficant impact on the environment have to get an environmental impact analysis before proceeding with the activities. The permit to carry out the activities comes from the related government official after studying the proposal and the environmental impact analysis and taking into account public recommendations.

Indonesia is also very concerned about the conservation of biological resources. Article 4 in the Law on Conservation of Biological Resources and its Ecosystem (13), stated that the government and community is responsible for conservation of biological resources and its ecosystem. Article 5 of the Law stated that conservation of biological resources and its ecosystem will be done through the following activities: protection of systems sustaining the habitat, conservation of plant and animal diversity and its ecosystem, and sustainable utilization of biological resources and its ecosystem.

In 1994, the Government of Indonesia ratified the Convention on Biological Diversity by Law No 5, 1994 (17) and in 2004, Indonesia is in progress to ratify the Cartagena Protocol. The agreement of the House of Representatives was given on July 17th, 2004, and on October 19th, 2004 the Republic of Indonesia ratify Cartagena Protocol with Law No 21, 2004.

Policy on Health

The Health policy as stated in the article 21 in the Law on Health (16), emphasized that the people shall be protected from foods and drinks which are not up to the standard health requirements, and packaged food shall be labeled containing the materials, its composition, date, month and year of expiration and other matters. Moreover, the Decree of the Minister of Health (1989) stated the compulsory registrations for packaged food before release into the market (3)

Policy on Food

In 1996 the Government of Indonesia for the first time issued the Law on Food (18), covering food safety, quality and nutrition as well as labeling, advertisement and food security.

The objectives of the Food Law are as follows:

1. the availability of foods which comply with food safety, quality, and nutrition requirements for public health protection,
2. the existence of fair and accountable trade,
3. the availability of foods with affordable price and accessibility to the general public.

The last objective is related to food security, which is a condition where high-quality, nutritious, and safe foods are available and accessible to each family household. Articles under the food safety chapter regulate food sanitation, food additives, foods derived from modified organisms and food irradiation, food packaging and contaminated foods. In term of foods derived from genetically modified organisms it is very clearly stated in article 13 that based on the precautionary approach the Government of Indonesia regulates that all GM-based Foods shall be assessed for food safety before their release into the market.

Policy on Agriculture

The Indonesian agricultural policy is stated in the Law on Systems for Plant Cultivation (14). Article 2 and 3 of the Law stated that the overall principle of Indonesian agriculture is be beneficial, environmental friendly and sustainable, while the objective is to increase and to widen the diversity of agricultural products to fulfill the need for food, garments, shelter, health and domestic industries in country and for export, thereby increasing the income and status of the farmer and to support widening opportunities for work and industry.

The primary aspect emphasized in the Law is to increase productivity, increase the farmer's standard of living, as well as to be environmental friendly and sustainable. The other aspect mentioned is the freedom of the farmer to choose their crop and culture system as long as they do not contradict public norms.

The agricultural policy is also reflected in the Law on Animal Husbandry and Animal Health (11) stating in article 3 the government's commitment to increase animal husbandry, while at the same time considering the animal's health. In the Article 3 in the Law on Fishery (12) it is also stated that Indonesia wants to reap the benefits from fishing in Indonesian territory in a sustainable way with an emphasis on environmental conservation.

The other aspects of the policy reflecting Indonesian policy on agriculture can be seen in the Law on Plant, Animal and Fish Quarantine (15). In article 3 of this Law, Indonesia states the policy and means for safeguarding Indonesian territory from various pest and diseases originated from plants, animals and fish introduced to Indonesian territory.

Policy on the Development of Science and Technology

As stated in the article 19 in the Law on Systems for Research, Development and Application of Science and Technology (21), the government is responsible for the development of basic science, strategic science and technology, as well as for increasing the capacity for research and development

which serves as a backbone for the capacity development of science and technology. In addition, the government is responsible for increasing the capability of social and cultural science in support of the development of science and technology. Furthermore, the government is responsible for the capacity building of technology-based industries to increase capacity for engineering capability, innovation and technology diffusion and also to promote markets for the products of research and development activities.

Agenda 21 for Indonesian Sustainable Development

In the Agenda for Indonesian Sustainable Development in the 21st century (23), in Article 17 for Biotechnology it is stated that the focus of biotechnology is to solve the priority problems in Indonesia especially related to agriculture, health, and the environment. However, the biotechnology approach will only be a success if supported by the development of infrastructure and national capacity building of biotechnology and the development of safety aspects of biotechnology to minimize unwanted negative impacts of biotechnology activities.

To achieve the objectives, the program is elaborated in the description and analysis of 5 sub programs as follows :

1. Agricultural Biotechnology to increase production of food, feed and renewable resources.
2. Medical Biotechnology to increase level of health, quality of life and environmental improvement.
3. Environmental Biotechnology.
4. Development of infrastructure for biotechnology.
5. Guidelines for the Safety of Biotechnology.

National Development Program

In the Law of the Five Year National Development Program 2000-2004 (20), it is stated that one of the government programs is to develop a food security system based on the diversity of food resources, institutions and local

culture in order to ensure food availability and nutrition in the amount and quality needed with an accessible price level, putting special concern on the increase of income for farmers and fishermen and the increase in production as regulated by Law.

In the Economic Development Program, there is also a special provision for a Program for Agribusiness Development with five main targets:

1. to increase productivity, quality and production of selected agricultural food commodities, horticulture, animal husbandry, fishery, estate crops and forestry;
2. to increase work availability and business opportunities in the agricultural and rural areas;
3. to increase added value for agriculture, fishery, estate crops, animal husbandry and forestry communities;
4. to increase public participation and private investment in the development of agriculture and rural areas;
5. to conserve and maintain natural resources and the environment.

Ratification of various environmental conventions

With the awareness of the importance of the international collaborations in conservation and sustainable development, Indonesia has ratified various International Conventions related to biodiversity as follows :

1. United Nations Convention on Biological Diversity (UNCBD), by Law No 5, 1994.
2. Cartagena Protocol on Biosafety
3. Convention on Wetlands of International Importance Especially as Waterfowl Habitat (RAMSAR)
4. Convention of International Trade of Endangered Species (CITES)

From the above mentioned articles in Indonesian Law, conclusions can be drawn that the national policy for biotechnology and biosafety has to be based on

the efforts to prevent and minimize negative impacts to the environment and human health and at the same time to achieve welfare for the people, by efforts to achieve food security through the increase of agricultural production in quantity and quality using appropriate technology. In short, this policy can be mentioned as: The Safe Use of Biotechnology, which is relevant to the precautionary approach of the Cartagena Protocol.

In order to achieve the safe use of biotechnology, the main goals of the National Biosafety Policy of the Republic of Indonesia are:

1. Develop a National Biosafety Framework and all its components, i.e. legislation, administration, information sharing, education, public awareness and participation, and research on biosafety, which represent parts of the system that need to be strengthened.
2. Ensure an adequate level of biosafety in transfer, handling and use of LMOs which may have adverse effects on conservation and sustainable use of biological diversity, taking into account risks to human health, and using the precautionary approach without putting constraints on the research and development of biotechnology in Indonesia.

III. **REGULATORY REGIME**

The development of a regulatory regime on biosafety of LMOs in Indonesia started from the research and technology sector, and later was developed by the agricultural sector and the environmental sector.

The development of a regulatory regime for genetic engineering was started in 1993 when the State Ministry on Research and Technology released a guideline on genetic engineering research. The emphasis of this guideline is on the control of research of genetically modified organisms (24).

In Indonesia, the need for biosafety regulation is well recognized. The decree of the Minister of Agriculture No. 85/Kpts/HK.330/9/1997 on the Provisions on Biosafety of Genetically Engineered Agricultural Biotechnology Products (GEABPs) was signed in September 1997 (4). This decree is intended to regulate and supervise the utilization of GEABPs. The scope of the decree covers the regulation of the kinds, requirements, procedures, rights and obligations, monitoring and reporting the utilization of GEABPs and their supervision. To implement the regulation, a Biosafety Committee (BC) was formed to give the suggestion, consideration or recommendation of a GEABP to the Minister of Agriculture whether it will be approved for utilization or denied. In addition, the Biosafety Technical Team (BTT) was formed to assist the BC in evaluating the application and carrying out a further technical study or test of a GEABP in a biosafety containment facility and/or contained field. The Guideline for Testing of the Biosafety of GEABPs consists of five series: General, Plants, Fish, Animal, and Microorganisms, which have been developed by the BTT. In 1999, in order to include food safety aspects, the decree was revised to become a Joint Decree of Four Ministers (Minister of Agriculture, Minister of Forestry and Estate Crop, Minister of Health, and State Minister of Food and Horticulture) on Biosafety and Food Safety of Genetically Engineered Agricultural Products. No: 998.1/Kpts/OT.210/9/99; 790.a/Kpts-IX/1999; 1145A/MENKES/SKB/IX/1999; 015A/ NmenegPHOR/09/1999 (24).

The decree covers Genetically Engineered Agricultural Products (GEAPs), defined as transgenic animals, materials originated from transgenic animals and

its processed products, transgenic fish, materials originating from them and their processed products, transgenic plants and their parts, and transgenic microorganisms.

The definition of the process of genetic engineering covers all attempts to carry out a deliberate change to the genome of living creatures by adding, deleting and/or changing the original structure of the genome by using recombinant DNA technology. The general provision of the decree is that the utilization of GEAPs originating from both domestic and foreign products must pay attention to and take into consideration the religious, ethical, socio-cultural and esthetical norms.

Both the BC and BTT were reformed to become the Biosafety and Food Safety Committee (BFSC) and the Biosafety and Food Safety Technical Team (BFSTT) respectively (10).

In this decree the Competent National Authorities are :

1. Minister of Agriculture for transgenic animals, transgenic fish, transgenic agricultural plants and transgenic microorganisms.
2. Minister of Forestry and Estate Crops for transgenic plants for forest and industrial crops.
3. Minister of Health for transgenic materials to be used directly as food or processing.

Another regulation directly connected with the use of transgenic materials is the Food Law (18). In this law there are special provisions on transgenic food and irradiated food. People producing food or using materials, food stuffs and/or food additives in the process of food production that originated from the process of genetic engineering shall submit the product to be tested for food safety related to human health before release to the market. Moreover, the government established the requirements and principles of research, development and the use of genetic engineering methods in activities related to food production and established the standards for assessments for food originated from genetic engineering (Article 13).

The distribution of processed foods, including processed foods derived from transgenic products, is regulated by ministerial decree, such as the Decree of the Minister of Health No 382/MEN.KES/PER/VI/1989 on compulsory registration for food (3). In this decree, before commercialization, processed food produced in Indonesia or imported in the retailed package, has to be registered to the Directorate General for Drug and Food Control. The packaged food will be labeled and the producer or importer has to guarantee the safety and quality of the food as well as the correctness of the label. In relation to processed food registration, recently a new decree which deals with the criteria and operational procedures for food product assessment required for registration has been issued (5).

Regarding food introduced into Indonesian territory, the government established the requirement that the food should have already been tested and examined and declared by the responsible agency in the exporting country to pass safety, quality and nutrition standards (Article 38) (18). Indonesia is the first country in ASEAN that introduced labeling for products containing GMOs, stated in the Government Regulation No 69, 1999 on Label and Advertisement for Food with the threshold level of 5% GMO content.

The Joint Decree of Four Ministers has to be updated because of changes with the organizations: at present the State Minister for Food and Horticulture no longer exists, the authority for estate crops is being moved to the Department of Agriculture and there is a new Department of Marine and Fishery, so for fish the competent authority will also be different. Furthermore, there are changes regarding the Department of Health: the Directorate General for Drug and Food Control was withdrawn from the Department and has become the National Agency for Drug and Food Control (NADFC), responsible for the safety aspects of food and medicine in Indonesia.

Aside from this, there are several provisions to be complied with in the Cartagena Protocol, such as the need for public participation and the Biosafety Clearing House. There is also a need to include the State Ministry of Environment to be responsible for release to the environment. In order to fulfill

these needs, the State Ministry of Environment, in cooperation with the Department of Agriculture and the NADFC and other stakeholders, has been drafting a Government Regulation on Biosafety for Genetically Engineered Products (6).

The form of the Government Regulation is chosen because it is a multi-sectoral regulation encompassing several Ministries and Non-Department Agencies, with the necessity to have flexibility in order to cope with the rapid development of biotechnology. If the regulation is in the form of Law, the necessary changes will have to be passed by the House of Representatives and will take a long time to make necessary adjustments. However, several NGOs in Indonesia have a different view and propose that it take the form of a Law, because while a Law is not flexible, it has a definite provision for liability and redress. Nevertheless, the government decided to choose the Government Regulation and put the liability and redress in a related Law. A Summary of the draft of the Government Regulation on Biosafety of Genetically Engineered Products is in Annex IV.

The Related Law in process is the Draft Law for the Management of Genetic Resources (7). Indonesia is one of the world's centers for megadiversity, therefore the Draft Law of the Management of Genetic Resources will deal with all aspects of the management of Genetic Resources in Indonesia for conservation and sustainable usage. The relation with modern biotechnology will emphasize the safe use of genetic resources while minimizing impacts on biodiversity as well as on the aspect of benefit sharing and law protection according to Article 8j and 15 of the Convention on Biological Diversity. The law is being developed by the State Ministry of Environment and is in the process of interdepartmental consultations; it is expected to be announced in late 2004 or early 2005. An inventory of regulations which are not related directly with LMOs is in Annex V.

Harmonization between ASEAN countries

Many ASEAN countries are actively involved in biotechnology research and have made substantial investments in agricultural biotechnology. It is expected that more genetically engineered crops and other food products will come into the market over the next few years. However, knowledge about the introduction of LMOs to the environment and the capacity for assessing environmental and food safety risks is still limited, together with the fact that technology is changing dynamically. Therefore the exchange of information among ASEAN member countries to understand the requirements of each country and to keep pace with new knowledge and experiences has gained interest, particularly in the areas of environmental risk assessment and potential long term impact on the environment, biodiversity and human health. The status of biosafety regulations in the ASEAN member countries are at different stages. Standards and regulations for agricultural biotechnology products need to be harmonized to reduce any possible friction and to ensure fair practice, to allow free movement, and to facilitate trade within ASEAN under the ASEAN free trade area (AFTA) (8,22).

The three bodies dealing with biotechnology and biosafety aspects are the ASEAN Ministers on Agriculture and Food (AMAF), the Committee on Science and Technology (COST) and the ASEAN Senior Officials on Environment (ASOEN). In an attempt to harmonize the regulation for agricultural biotechnology products in the sub-region, several meetings at the ministerial level have been conducted. In 1999 at the 21st meeting of the AMAF, the ministers endorsed the ASEAN guidelines on risk assessment of agriculture-related Genetically Modified Organism (GMO) that provide a common framework to undertake risk assessment of GMOs. However, this guideline is not legally binding. The ASEAN guideline and the Indonesian guidelines for biosafety and food safety were adopted from the GMAC's Australian guidelines.

The adoption of the ASEAN harmonized guidelines on the risk assessment of agriculture-related GMOs by AMAF is a first step that has shown the region's cooperative effort to face the global development in agricultural

biotechnology. These sets of guidelines are not legally binding and have no precedence on national legislation. However, they provide a very good framework for science-based risk assessment for ASEAN member countries. The Guidelines are aimed at providing ASEAN member countries with a common understanding and approach to undertake scientific evaluations of applications for the release of agriculture-related GMOs in their countries.

They have attachments with a step-by-step checklist to guide regulators and risk managers on the assessment of products. The Guidelines describe the procedures for notification, approval and registration of agriculture-related GMOs. But they exclude compensation and liability issues. They do not discuss labeling and there were no socioeconomic or religious factors discussed in the document. In addition, these guidelines address issues related to food safety.

The Guidelines also address the need for each country to establish its own National Authority on Genetic Modification (NAGM) and the roles and responsibilities of this authority in regulating agricultural GMOs. The establishment of a NAGM, which will consist of representatives from national agencies involved in agriculture, trade, economies, environment, health, science and technology and/or any other agencies and related sectors, is needed in each member country to oversee the implementation of the guidelines.

A risk assessment questionnaire contained in the Guidelines spells out the information required from proponents who wish to introduce agriculture-related GMOs in the region. The questionnaire was developed from existing risk assessment tools used by other countries such as Australia, Canada and the US. It will assist individual NAGMs to make decisions based on the information provided by the Proponent in its application. Information on approval of agriculture-related GMOs would be deposited at the ASEAN Secretariat. This will provide a database and will assist member countries to evaluate similar applications more easily (8).

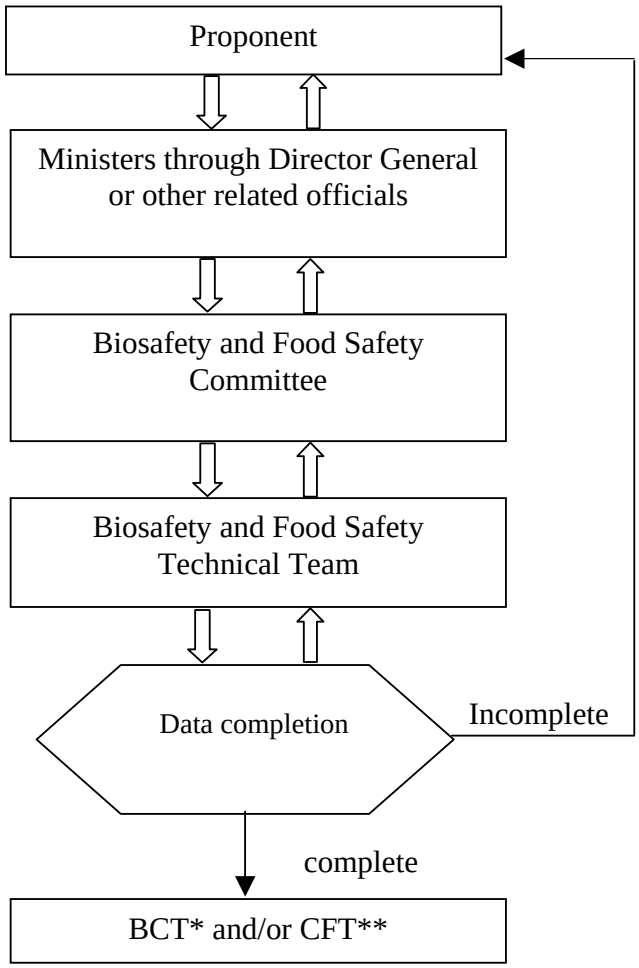
IV. SYSTEMS TO HANDLE NOTIFICATIONS OR REQUESTS FOR AUTHORIZATION

Based on the existing regulation (10), a person applying for the introduction of a GEAP has to submit a written application for the biosafety and food safety assessment using specific forms (model A) (Annex VIII):

1. The Minister of Agriculture, in this case the Director General of Animal Husbandry for animals, vaccine culture, antisera, probiotic, and biological material for transgenic animals;
2. The Minister of Agriculture, in this case the Director General of Fishery for transgenic fish and materials originating from it;
3. The Minister of Agriculture, in this case the Director General of Food Crops and Horticulture for transgenic food crops and horticultural crops, and their parts;
4. The Minister of Agriculture, in this case the Director General of Plantation for plantation plants and transgenic industrial crops as well as their parts;
5. The Minister of Agriculture, in this case the Director of the Center of Quarantine for microorganisms of the transgenic biological agents;
6. The Minister of Agriculture, in this case the Pesticide Commission for microorganisms of the transgenic biological agents;
7. The Minister of Agriculture, in this case the Director General of the Agency for Agricultural Research and Development for GEABPs not included in ad 1,2,3,4 and 5.

The application must be accompanied by information on the GEAP as mentioned in Annex VII, using MODEL A form (Annex VIII) along with completion of the relevant questionnaires in Annex IX. After receiving the application, the abovementioned official requests the considerations on the technical aspects of biosafety and/or food safety from the Biosafety and Food Safety Committee (BFSC), the special committee founded with the membership in the Annex VI. The BFSC examines the application for its completion, and corresponds with the

proponent to complete the applications. After getting all of the complete information needed, the BFSC asks the Biosafety and Food Safety Technical Team (BFSTT) to carry out an appropriate technical study (risk assessment and risk management). The BFSTT is obligated to submit a report on the result of the risk assessment and risk management study to the BFSC. On the basis of the report on the risk assessment and risk management results, the BFSC submits its suggestions, considerations or recommendations to the official above. In the case that the GEAP has once been utilized in Indonesia, the BFSC will give a suggestion, consideration or recommendation to the abovementioned official that the GEAP was already approved for utilization. (Figure 1)



BCT* = Biosafety Containment Test. CFT** = Contained Field Test

Figure 1. Diagram of existing system for notification or requests for authorization.

Several Guidelines for Testing for the existing system were developed, namely Guidelines for Biosafety Testing of Genetically Engineered Agricultural Biotechnology Products Assessment in five series: General, Plant, Animal, Fish, and Microorganisms.

The existing system has already been put to the test because there were several proposals for transgenic utilization proposed and processed. There is now a need to improve the system and a need to develop new regulations as the Government Regulation on Biosafety of Genetically Engineered Products (GEPs). Biosafety in this regulation consists of environment safety, food safety and feed safety.

This new regulation arises from several needs, including :

1. Institutional needs as mentioned in II, where the related agencies are undergoing reorganization and the need to include the Ministry of Environment.
2. Lessons learned from the registration experience so far.
3. Compliance with the Cartagena Protocol.

There are several distinct changes in the draft of the new legislation as follows:

A. National Competent Authorities

1. The Minister of Environment will be responsible for the environmental safety of GEPs which will be released deliberately to the environment.
2. The Minister related to the commodities: Minister of Agriculture, Minister of Forestry, Minister of Marine and Fishery as authorities regulating GEP release to the field after declared environmentally safe by the Minister of Environment.
3. The NADFC for GEPs intended to be use directly as food or to be processed.
4. The Ministry of Agriculture for GEPs intended to be use directly as feed.

B. Structure and membership of the BFSC.

The existing BFSC consists of 29 ex officio members representing various related organizations including NGOs and founded by the joint decree of several ministers. Reality shows that it was not easy to gather the BFSC since 29 ex officio members are obviously very busy with their own activities in their organizations, therefore in the new regulation it will be proposed that although representation is still necessary, the membership will not be ex officio but will have an emphasis more on expertise. The future committee and technical team will be the Biosafety Committee (BC) and Biosafety Technical Team (BTT). Moreover the BC will be founded by Presidential decree based on the recommendations from related Ministries through the Minister of Environment. The BTT will consist of various experts related to GEPs. The status, duty, membership and obligation of the BTT will be decided by the Chairman of the BC after considering recommendations from related Ministers and the Chairman of the NADFC.

C. Timeframe for decision making.

There will be a timeframe in the new regulation especially related to administrative matters such as acknowledgement of the receipt of the proposal and also related to the document assessment, such as the timeframe for recommendation and deliberation of the BC after submission of the results from study of risk management and risk assessment by the BTT.

D. Indonesian Biosafety Clearing House.

The Indonesian Biosafety Clearing House (BCH) is already established and acts as source of information for the stakeholders. At present there is a website of the Biosafety Clearing House maintained by Research Center for Biotechnology, Indonesian Institute for Science with the url: www.bchindonesia.org (26).

In the Draft of Government Regulation on Biosafety of Genetically Engineered Products (6), the BCH is a part of the Biosafety Committee with a duty to :

1. maintain and serve information to the public about procedures, acceptance of proposals, process and summary of result assessments
2. to receive inputs from the public and to asses the input and submit it to the Committee
3. to provide information about the draft of the recommendation from the Biosafety Committee which will be submitted to the related Minister and/or Non Departmental Government Institutions; and to provide information about the decision of the related Minister or non departmental government institutions about proposals which have been assessed to the public.

The website contains :

1. Introduction to BCH Indonesia (papers and presentations on BCH Indonesia).
2. Regulations (regulations directly related to biosafety)
3. Guidelines for Biosafety and Food Safety Assessments of GEAPs.
4. Domestic decisions (released GEAP in Indonesia, Bt cotton from Monsanto)
5. Contact address of BCH Indonesia (for public and related institutions).
6. Roster of experts (experts related to biosafety of GEAPs in Indonesia).
7. Discussion forum (for public opinion and news from BCH Indonesia).
8. Related scientific papers (published papers in peer-reviewed journals).
9. Links

Between the date the BCH was established in March 2003, until June 2004, the website had 50 to 200 hits per month. Most of the access comes from Indonesia, about 20% of the hits are from ASEAN countries, while about 5% are from the USA. Most of the content is still in Bahasa Indonesia, however, efforts will be made to serve the data in two languages i.e. Indonesian and English.

The Summary of the Government Regulation on Biosafety of Genetically Engineered Products is provided in Annex IV.

E. Mechanism for Public Participation

There will be a special model of public participation in the new regulation to comply with the Cartagena Protocol, through the Biosafety Clearing House (BCH). The Biosafety Clearing House is a part of the Biosafety Committee. After the BTT finishes with the biosafety assessment of a GEP, the Committee will assign the BCH to announce the summary of the results from the BTT's assessments of the GEP through mass media, printed or electronically, and the official gazette of the BC for 60 days starting from the receipt of the results of the technical assessment from the BTT. For 60 days the public will have an opportunity to respond in writing to the BCH. Based on the results of the technical assessment and the public response, the BC will give a recommendation of safe or unsafe for environmental release to the Minister of Environment and safe or unsafe for consumption to the related Ministers/Non departmental government institutions for the GEP intended to be use directly for food, feed and processing.

The new diagram for the notification and request for authorizations will be as follows

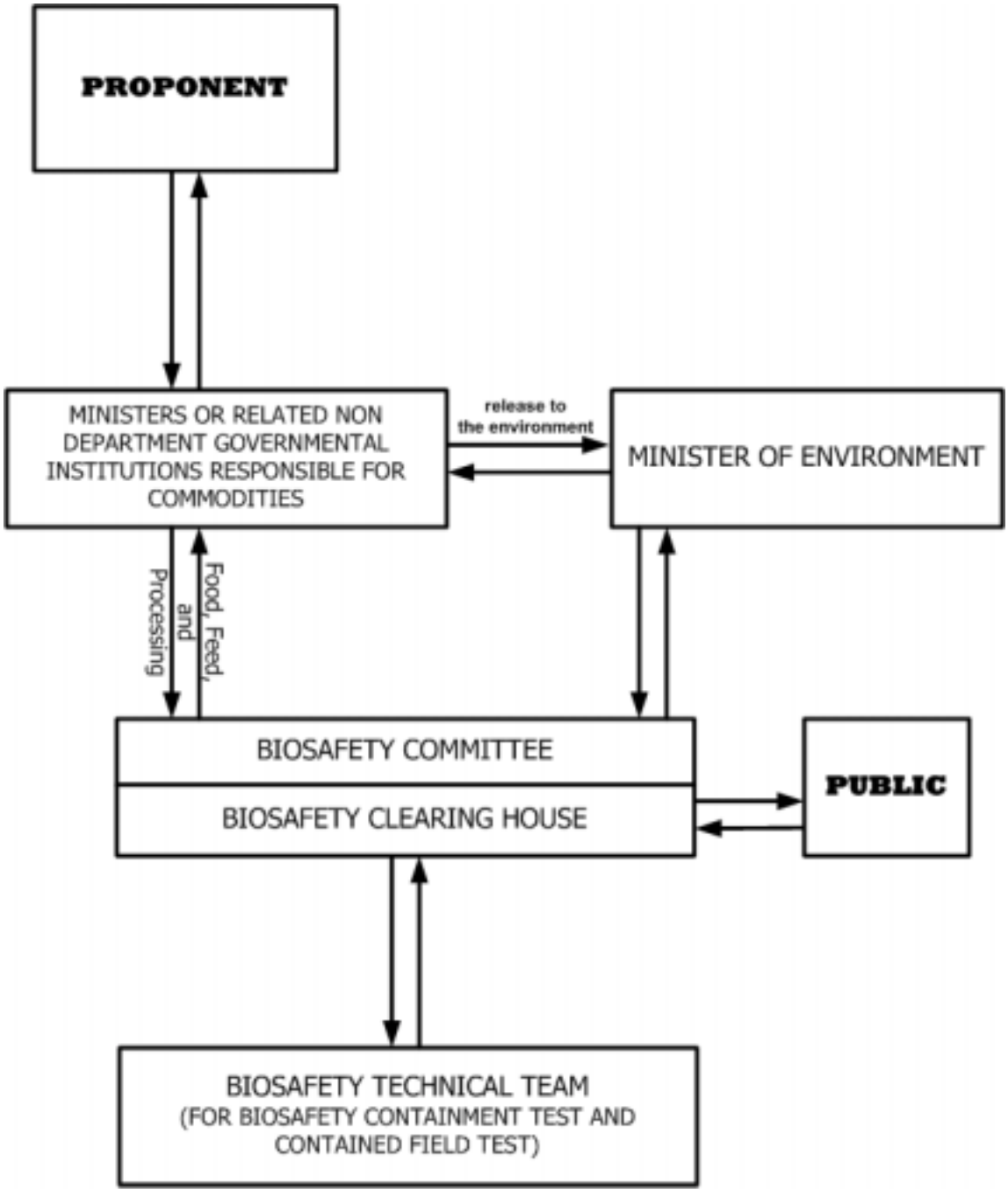


Figure 2. Diagram for systems to handle notifications and requests for authorizations based on the Draft of Government Regulation for Biosafety of Genetically Engineered Products.

V. MONITORING AND ENFORCEMENT.

In the existing system, the provision in the Joint Decree of Four Ministers (10) states that any person or legal entity who or which has obtained approval for the utilization of a GEAP is obligated to submit a periodical report once every year or any time when required or in the event of biosafety and/or food safety harm, to the related National Competent Authority. The National Competent Authority shall monitor the level of GEAP utilization assisted by:

1. The Supervisor of Animal Drugs, Pest and Disease Observer of the Agency for Monitoring of Animal Disease, Animal Stock Supervisor, Veterinarian assigned to the Animal Slaughterhouse/Poultry Slaughterhouse, Veterinarian, Supervisor for Fodder, for transgenic animals and materials originating from them;
2. Supervisor of Fish Resources for transgenic fish and materials originating from it;
3. Insect Pests and Diseases Observer, Seed Supervisor, Pesticide Supervisor for transgenic plants and transgenic microorganisms.

Moreover the BFSC, with the assistance of the BFSTT, shall monitor, evaluate and assess the biosafety and food safety of the impact of GEAP utilization after being released and report the results to the related National Competent Authority. The mechanisms of monitoring and controlling of the GEAP utilization shall be established by related National Competent Authorities (Article 44 and 45). When the GEAP causes harm to the environment or is proven to be toxic/allergenic, the person or legal entity who or which has obtained approval for the utilization of the GEAP is obligated to participate in the control and rectification (Article 43).

In the draft of the Government Regulation of Biosafety for Genetically Engineered Products the monitoring will be performed as follows:

1. Monitoring will be done by the relevant National Competent Authority
2. The Minister of Environment, assisted by the BC, and taking into account recommendations from related Ministers, shall establish guidelines for the impact monitoring and risk management of GEPs,
3. In the event of harm to the environment or toxicity/allergenicity for food or feed, the proponent is obligated to report to the relevant National Competent Authority. Communities and consumers are also being asked to monitor and report if the release of a GEP causes harm to the environment or is toxic/allergenic as food or feed.
4. Upon receiving the report the relevant National Competent Authority will ask the BC to check the accuracy of the report.
5. When the BC reports about the harm to the environment or if a GEP is toxic/allergenic as food or feed, the National Competent Authority may withdraw the release permit.
6. When a GEP causes harm to the environment and/or is toxic/allergenic as food or feed, the entity responsible for the activities shall be held responsible to control, manage and withdraw the related GEP from the environment and market.

VI. MECHANISMS FOR PROMOTING AND FACILITATING PUBLIC AWARENESS, EDUCATION AND PARTICIPATION.

Results from various surveys show that the awareness and the level of knowledge about GEPs is very low and mostly formed by the fear of the unknown due to the large amount of adversely presented and scandalous information on GEPs made available through the mass media, and enhanced by the lack of understanding of the basic facts behind modern biotechnology products (2). However, in general, it was felt that the importance of the issue for the general public is moderate and lower than other issues such as food price. Therefore effective mechanisms for promoting and facilitating public awareness, education and participation, including mechanisms for informing and involving the public in the development and implementation of the national biosafety framework, are badly needed in order to provide the public with unbiased information and to enable effective participation (2).

In the existing system there is no provision for promoting and facilitating public awareness, education and participation. Public participation is done by involving several NGOs such as the Foundation for Biodiversity, Foundations for Consumers, and the Indonesian Farmers Association in the NBFSC, along with several seminars held for public consultation before the BFSC submits the recommendations to the related Ministers. Involving NGOs as a member of the Committee was not a good practice since NGOs are not able to give scientific recommendations when being asked and NGOs do not want to be a part of the Committee recommending the release of GEPs to the environment. In the draft of the Government Regulation the mechanisms for public participation will be done by announcing the draft of the recommendations of the BC through the Biosafety Clearing House and announcement through brochures and pamphlets in the related government's office. Moreover, the public will be given 60 days to respond to the announcement and the BC has to then answer the concerns.

Effective public education also has to be done through other efforts, e.g. by cooperating with organizations such as Universities, Research Institutes, Professional Organizations through the development of modules for public education about biotechnology and biosafety. The materials developed can be in the form of written popular material such as brochures, pamphlets, booklets or teaching modules for high school and university. It is expected that an increase in public knowledge will encourage and enable effective public participation.

In relation to the biosafety issues, the primary ways of informing the public are electronic media such as the internet, programs on radio and television, printed media such as publications and leaflets; as well as through direct communications and meetings such as workshops and specialized courses and open meetings of the Biosafety Committee.

In order to raise public awareness and knowledge, the following activities are recommended:

1. Provision of information on the basic facts behind modern biotechnology by mass media with the help of popular science writers as well as publications in specialized magazines (agricultural, health, sciences) and popular publications such as daily newspapers, and/or weekly magazines.
2. Public education with the help of qualified intermediaries like science teachers at schools should be carried out in cooperation with professional organizations such as the Indonesian Biotechnology Consortiums.
3. Increasing public participation in decision-making processes can be facilitated through local government involvement, farmer organizations such as Indonesian Farmers Association (Himpunan Kerukunan Tani Indonesia) and consumers associations.
4. The role of the Biosafety Clearing House (www.bchindonesia.org) for providing information to the stakeholders shall be maintained and the effectiveness has to be increased.

Goals and Measures

Public awareness and participation in biosafety as a part of environmental education should be developed further in relation to the policies of respective sectors, especially with the Environmental Policy as the sector responsible for implementation of international biodiversity and biosafety related treaties.

In the near-term, the activities identified as necessary to be accomplished are:

1. Developing a program on public education and awareness in biosafety and ensuring its inter-linkage to other related programs.
2. Training scientists, science teachers and other possible trainers in public education and communications, in order to enhance their capacity to educate the public on biosafety issues.
3. Ensuring information sharing on risk assessment and risk management for GEPs.
4. Developing regional cooperation especially within ASEAN countries regarding GEPs, as well as cooperating with international organizations.

VII. CONCLUDING REMARKS

From the above presentation it can be concluded that

1) Indonesia needs a sound and workable biosafety regulation based on science to be able to reap benefits from biotechnology and at the same time guard the environment and human health. The existing regulation needs to be updated to include wider stakeholder participation and to comply with the Cartagena Protocol.
2) In order to implement the Cartagena Protocol as well as to update the existing regulation, Indonesia is in the process of developing a framework, and the new framework will be based on the Government Regulation on Biosafety of Genetical Engineering Products.
3) One of the main components of the framework is public participation. To enable effective public participation, public awareness and public education on biosafety have to be developed.
4) Considering the existing capacity for biosafety implementation, efforts to strengthen capacity for biosafety implementation for all stakeholders at the level of individual, institution and system is urgently needed.

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Annex I

Organization of the Project for the Development of the National Biosafety Framework for Indonesia

The National Executing Agency for the UNEP-GEF project:

State Ministry for the Environment of Indonesia
Jalan D.I. Panjaitan Kav. 42 Jakarta 13410,
Tel: (+62) (0)21 858 0111, Fax: (+62) (0)21 858 0111
Contact persons at the start of the project: Dra. Liana Bratasida, M.Si., Deputy Minister for Environmental Conservation (chmcbdri@rad.net.id); Budi Satyawan Wardhana (iwan_wardhana@yahoo.com); Due to the tour of duty, in December 2003, Dra Liana Bratasida M. Si was replaced by Ir. Utami Andayani, MS (utamikun@yahoo.com), Assistant Deputy for Biodiversity.

National Project Coordinator : Dr Tantono Subagyo tsubagyo@link.net.id
Building B 4th Floor, State Ministry for the Environment
Jalan D.I. Panjaitan Kav. 42 Jakarta 13410, Indonesia

The National Coordinating Committee consisted of 16 members as follows:

Table 1. Members of the National Coordinating Committee

Name	Representing
Prof. Dr. Amin Soebandrio (Chairman)	Assistant Deputy for Medicine and Health Science, State Ministry for Research and Technology
Prof. Dr. Daud Silalahi	Professor at Law, University of Padjadjaran
Prof. Dr. Dedi Fardiaz	Deputy Chairman for Food Safety and Hazardous Substance Control, National Agency for Drug and Food Control.
Prof. Dr. Deddy Muhtadi	Professor in Food Science, Bogor Agriculture University
Dr Pratiwi Sudharmono	Microbiologist, University of Indonesia
Dr. Susono Saono	Microbiologist, Indonesian Institute of Sciences

Dr. Sutrisno	Director, the Indonesian Center for Agricultural Biotechnology and Genetic Resources Research and Development, Department of Agriculture
Dr. M. Herman	Molecular Biologist, the Indonesian Center for Agricultural Biotechnology and Genetic Resources Research and Development, Department of Agriculture
Ir Utami Andayani, MSi	Assistant Deputy for Biodiversity, Deputy for Environmental Conservation, State Ministry for the Environment.
Ir. Budi Satyawan Wardhana	Division for Biosafety, Assistant Deputy for Biodiversity, Deputy for Environmental Conservation, State Ministry for the Environment.
Dr Mawarwati Jamaludin	Permanent Secretary for the National Agency for Drug and Food Control.
Ir Kanaan Adikusumah	Director for Import, Directorate General for Foreign Trade, Department of Industry and Trade
Dr Kartika Adiwilaga	Representative from Industry: Formerly Regional Manager for South East Asia, Monsanto, later moved to Nestle Industries.
Dr. Anida Haryatmo	Director of Program, Foundation for Biodiversity, NGO for Biodiversity Conservation
Dr. Setijati Sastrapradja	Naturindo, NGO for Biodiversity Conservation
Dr. Hari Hartiko	Biochemist, Faculty of Biology, Gadjah Mada University

Later, due to retirement, Dr. Hari Hartiko resigned from the Committee.

Annex II

Table 2. Modern biotechnology research and development in several institutions in Indonesia (Translated and modified from Mulya, et al, 2003 (24)).

Commodity	Research Aspects	Institution
Plants		
Rice	Resistance to stem borer	RCB-IIS
		ICABIOGRAD
	Resistance to tungro disease	Sebelas Maret University – Surakarta
	Resistance to blast disease	RCB-IIS
	Resistance to drought	RCB-IIS and ICABIOGRAD
Soybean	Resistance to pod borer	Udayana University
	Increasing albumin content	Udayana University
	Increasing yield	Udayana University
Cassava	Starch composition	RCB-IIS
Peanut	Resistance to PsTV disease	ICABIOGRAD
	Resistance to PsTV disease	Bogor Agriculture University
Cabbage	Resistance to disease	Gadjah Mada University and Airlangga University
Pepper	Resistance to disease	Bogor Agriculture University
	Ketahanan terhadap penyakit bakteri	Bogor Agriculture University
Papaya	Delay ripening	ICABIOGRAD
	Resistance to PRSV disease	ICABIOGRAD
Citrus	Resistance to CVPD disease	Udayana University
Cocoa	Resistance to pod borer	Res Institute for Estate Crops Biotechnology

Commodity	Research Aspects	Institution
Coffee	Resistance to disease	Res Institute for Estate Crops Biotechnology
Sugarcane	Increasing sugar content	Government Estate Crops XI
	Resistance to drought	Government Estate Crops XI
		Jember University
Teak	Quality	Bandung Technology Institute
	Pest resistance	PT Indah Kiat (private company)
Paraserian-thes falcataria	Pest resistance	RCB-IIS
Animal		
Chicken	Mapping of genetic diversity	Diponegoro University
Cattle	Gene mapping for production	Sebelas Maret University Surakarta
	Mapping and cloning gene for improvement of local cattle	Brawijaya University Malang
	Selection of local cattle for meat production through molecular markers	RCB-IIS
Lamb	Resistance to pathogenic worms	Ind Res Inst for Veterinary Science and RCB-IIS
Fish	Mapping of genetic diversity	Brawijaya University
Microbes		
Fungi	Molecular analysis of pathogenic fungi	Res Institute for Estate Crops Biotechnology
	Gene marker for chitinase	Res Institute for Estate Crops Biotechnology
Bacteria	Overexpression of thermophyllic enzyme	Bandung Technology Institute

Annex III

Table 3. Legal status for assessment and utilization of Genetically Engineered Products in Indonesia (Translated and modified from Mulya, et al, 2003 (24))

Commodity	Improved traits	Proponent	BCT*	CFT*	Results of BFSTT Assessment	Recommendation from BFSC	Multi-location trial*	Status
Corn	Pest resistance	Dupont / Pioneer	Done	_		_	_	_
	Pest resistance	Monsanto	Done	Done	Safe for environment	Safe for environment	-	-
	Herbicide tolerance	Monsanto	Done	Done	Safe for environment and food	Safe for environment	Done	-
Cotton	Pest resistance	Monsanto	Done	Done		Released	Done	Released
	Herbicide tolerance	Monsanto	Done	Done	Safe for environment	Safe for environment	Done	-
Soybean	Herbicide tolerance	Monsanto	Done	Done	Safe for environment	Safe for environment	Done	-
Ronozyme	Enzymes for feed	PT Rosindo			Safe for environment	Safe for environment	-	-
Finase L and Finase P	Enzymes for feed	PT Behlen Meyer			Safe for environment	Safe for environment	-	-

*** BCT = Biosafety Containment Test, *CFT = Contained Field Test,**
****Multilocation trial under Law on System for Plant Cultivation.**

Annex IV

Summary of the Draft of Government Regulations on Biosafety of Genetically Engineered Products in Indonesia.

Disclaimer : The Government Regulations on Biosafety of the Genetically Engineered Products in Indonesia is still in the discussions between related Ministries and several changes might happen as necessary

I. General Provision

Definition:

1. Biosafety : Term covering Environmental Safety, Food Safety and Feed Safety including Safety for Human Health
2. Genetically Engineered Products (GEPs): Living organisms, its parts, and/or processed products which have new genetic structure resulting from the application of modern biotechnology.
3. Modern biotechnology : Application of genetic engineering including in vitro nucleic acid techniques and cell fusion from two kinds of organisms or more outside the taxonomic family.

Scope of the regulation :

1. kinds and requirements of GEPs
2. research and development of GEPs
3. introduction of GEPs
4. assessment, release and utilization of GEPs
5. control and monitoring of GEPs
6. institution
7. financial arrangements and
8. sanctions

III. Kinds of GEPs include :

1. Transgenic animals, materials originating from them and their processed products;
2. Transgenic fish, materials originating from them and their processed products;
3. Transgenic plants, their parts and their processed products; and
4. Transgenic microorganisms.

IV.Requirements of GEPs:

1. A GEP from Indonesia or originated from abroad which will be assessed and/or tested for release or to be marketed in Indonesia has to be accompanied with basic information that the product fulfills the requirements of being safe to the environment, and safe to be used as food or feed
2. Basic information as a requirement for achieving the safety standards of the environment include:
    a. description and intents of utilization
    b. genetic and phenotype modification expected have to be detected
    c. clear identity of taxonomy, physiology and reproduction of the GEP
    d. clear and complete identity of organisms used a gene source
    e. genetical engineering methods used have to follow standard procedures and be scientifically acceptable
    f. clear detail of the molecular characteristics of the GEP
    g. Stable expression of the gene transformed to the said GEP
    h. Information on the method of eradication in case of unwanted deviation
3. Basic information as a requirement for achieving the safety standards of the utilization as food and feed include:
    a. The genetic engineering methods employed must follow standard procedures and be scientifically acceptable
    b. the nutritional content of the GEP has to be equivalent to the non GEP
    c. the content of toxic substances, antinutrition agent, and allergenic substances in the GEP have to be substantially equivalent to the non GEP counterparts
    d. the content of carbohydrates, protein, ash, lipid, fiber, amino acid, minerals, and vitamins have to substantially equivalent to the non GEP counterparts
    e. protein encoded from the transferred gene has to be non allergenic

V. GEPs for research and development

1. the government facilitates and performs research and development to produce GEPs in Indonesia

2. every entity doing research and development has to prevent and/or manage the negative impacts of their activities to the environment; and the nutritional content of the GEP has to be equivalent to the non GEP

3. the research and development of a GEP has be performed in the laboratory, contained biosafety facility and/or contained field

4. before release to the environment, a GEP resulting from research and development has to undergo an efficacy test and fulfill the biosafety requirements

VI. Introduction of a GEP from another country

1. every entity who wants to introduce a kind of GEP for the first time must ask permission from the related Minister or non departmental government institution responsible for the related commodity

2. the request to introduce a GEP has to be submitted together with documents indicating fulfillment of the biosafety, food safety and feed safety standards

3. besides the requirements in ad 2. documents of the certificate of free trade in the country of origin, and documentation containing risk assessment and risk management by institutions where the risk assesments has been done, have to be submitted as well

4. after documents from ad 2 and ad 3 are complete, the Ministers or Chairman of the non departmental government institutions send the document to the Minister of Environment and ask for a recommendation of the safety to the environment

5. the Minister or non departmental government institution has to make a decision based on the biosafety recommendation from the Ministry of Environment

6. in the formulation of a recommendation, the Minister of Environment will be assisted by the Biosafety Committee

VI. Assesment, release and utilization of a GEP

1. all of the assessments for release of the GEP are done by the Biosafety Committee (BC)
2. in case of technical assesments, the Biosafety Committee will be assisted by the Biosafety Technical Team (BTT) responsible for assessment of the documents and further study in the laboratory and/or biosafety containment facility and/or contained field test whenever necessary

3. Guidelines for the Risk Assesment and Risk Management for Biosafety will be established by Presidential Decree

4. the evaluation result and result of the technical assessment by BTT will be submitted to the BC as a base for recommendation, 7 days after the end of the technical assessment

5. upon receiving results in ad 3, the BC will ask the Biosafety Clearing House (BCH) to announce the request, process and summary of the result of the assessment to the public in a place accessible to the public for 60 days, to give an opportunity to the public to respond in writing

6. the BCH will submit the public response (if any) to the BC

7. after deliberation, the BC will prepare a draft of recommendation for the Minister of Environment or the related Minister or Chairman of the non departmental government organizations containing the result of the technical assessment and public response together with either biosafety recommendations or refusal and reasons of the said recommendations

8. in case of the release to the environment, the Minister of Environment will give a biosafety recommendation to the related Minister or Chairman of the non departmental government institutions responsible for the related commodity

9. after fulfillment of the necessary requirements according to the existing regulations, the related Minister or Chairman of the non departmental government institution will make a decision for the release to the environment or refusal of the request

VII. Control and monitoring

1. Control and monitoring will be performed by the related Minister or Chairman of the non departmental government institution according to the recent rule and regulation

2. the Guideline for Control and Monitoring of the Impacts of GEPs to the Environment will be established by the Minister of Environment based on the input and recommendation from the BC

3. Control and monitoring will be performed by the related Minister or Chairman of the non departmental government institution according to the recent rule and regulation

4. A Guideline for Control and Monitoring of the Impacts to the Environment will be established by the Minister of Environment based on the input and recommendation from the BC and related Minister and Chairman of the non departmental government institution

5. Control and monitoring will also be done by the public and consumers through inputs to the responsible organization

6. in case of unwanted deviation happening, the proponent must report the case to the Minister of Environment

7. in case of report of unwanted deviation, the Minister of Environment will ask the BC to verify, and if it is proven, the Minister of Environment will recommend to the related Minister or non departmental government organization to withdraw the product

8. in case of unwanted deviation happening, the entity responsible for the activities have to be responsible for controlling and withdrawing the GEP from the market and/or the environment

IX. Other matters

1. The structure, membership, duty and function of the BC will be established by Presidential decree based on the recommendation from the Minister of Environment and related Ministers and related non departmental government institutions

2. The structure, membership, duty and function of the BTT will be established by the Chairman of the BC taking into account the recommendation from the related Ministers and Chairman of the non departmental government institutions

Annex V

Table 3. Regulations related to the use of GEPs for commercial usage as seeds or for animal husbandry or fishery. (Translated and modified from Mulya, et al, 2003 (22))

No	Regulations	Regulated aspects	Relations
	Law		
	1. Law No 6/67	Animal husbandry and animal heath.	Animals to be reared commercially, biological materials for animals
	2. Law No 9/85	The use and management of fish resources	Release of new fish varieties
	3. Law No 5/90	Conservation of Genetic Resources	Conservation of flora and fauna
	4. Law No 12/92	Systems for Plant Culture	Various aspects of agriculture including release of new varieties of agricultural crops
	5. Law No 16/92	Quarantine for animals, fish and plants.	To protect animal, fish and plants from foreign pest and diseases, and from invasive alien species
	6. Law No 5/94	Ratifications of the Convention on Biological Diversity	Conservation, management and utilization of genetic resources
	8. Law No 44/99	Forestry	Forest management with new forest varieties
	9. Law No 23/97	Environment	Biological environment
	10.Law No 29/2000	Plant Variety Protection	Intellectual property protection of new plant varieties

	Government Regulations		
	1. GR No. 78/92	Production, release on the market and utilization of biological materials for animals.	If the production involves modern biotechnology
	2. GR No. 6/95	Plant Protections	Pest Control using Natural Enemies
	3. GR No. 44/95	Seeds for Crops	Imports/exports, breeding and release of new varieties
	4. GR No. 27/99	Environmental Impact Analysis	Analysis of the risk to the environment
	6. GR No. 29/2000	Animal Quarantine	To prevent foreign diseases entering Indonesian territory
	7. GR No. 14/2002	Plant Quarantine	To prevent foreign plant pests and diseases entering Indonesian territory
	8. GR No. 15/2002	Fish Quarantine	To prevent foreign fish pests and diseases entering Indonesian territory
	Decree of the Minister of Agriculture		
	1. No 737/Kpts/ TP.240/9 /98 Amendment of Decree No 902 /Kpts/TP.240 /12/96	Testing, evaluation and release of new plant varieties	Procedure for testing, evaluation and release of new plant varieties
	3. No 26/KPTS/ OT.210 /1/1998	Importation of fish fingerlings	Procedures for importation of fish fingerlings to be reared commercially in Indonesia

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Annex VI

MEMBERSHIP, DUTY AND RESPONSIBILITY OF THE BIOSAFETY AND FOOD SAFETY COMMITTEE (BFSC)

A. MEMBERSHIP

The membership of the BFSC is as follows:

I.	Chairman I	:	Director General of the Agency for Agricultural Research and Development, Department of Agriculture;
	Chairman II	:	Director General of the Agency for Forestry and Estate Crops Research and Development, Department of Forestry and Estate Crops;
	Chairman III	:	Director General of Food and Drug Inspection, Department of Health;
	Chairman IV	:	Assistant to the State Minister of the Food and Horticulture Division on Quality and Food Safety;
II.	Secretary I	:	Director of the Central Research Institute for Food Crops, the Agency for Agricultural Research and Development, Department of Agriculture;
	Secretary II	:	Director of the Directorate of Food and Beverage Inspection, Directorate General of Food and Drug Inspection, Department of Health;
	Secretary III		Director of the Central Research Institute for Estate Crops, Agency for Forestry and Estate Crops Research and Development, Department of Forestry and Estate Crops;

III. Member :

1. Director of the Research and Development Center for Biotechnology, Indonesian Science Institute (LIPI);
2. Manager of the Center for Assessment and Application of Industrial and Agricultural Biotechnology, Agency for Assessment and Application of Technology;
3. Director of the Center for Drug and Food Investigation, Directorate General of Food and Drug Inspection, Department of Health;
4. Director of the Research and Development Center for Nutrition, Department of Health;
5. Director of the Research and Development Center for Pharmaceutical, Department of Health;
6. Director of Animal Health, Directorate General of Animal Husbandry, Department of Agriculture;
7. Assistant to Deputy I Concerning Environment Conservation and Development, State Ministry of Environment;
8. Director of the Central Research Institute for Animal Husbandry, the Agency for Agricultural Research and Development, Department of Agriculture;
9. Director of the Central Research Institute for Horticulture Crops, the Agency for Agricultural Research and Development, Department of Agriculture;
10. Director of the Central Research Institute for Fishery, the Agency for Agricultural Research and Development, Department of Agriculture;
11. Director of the Legal Bureau, Department of Agriculture;
12. Director of the Legal Bureau, Department of Health;
13. Assistant to the Deputy State Minister of Food and Horticulture, Division of Quality and Food Safety;

14. Director of the Inter University Center for Biotechnology, Bogor Agricultural Institute;
15. Chairman of the Indonesian Biotechnology Consortium;
16. Chairman of the Indonesian Society for Agricultural Biotechnology;
17. Chairman of the Indonesian Society for Breeding;
18. Chairman of the National Commission for Germplasm;
19. Chairman of the KEHATI Foundation;
20. Chairman of the Indonesian Consumer Foundation;
21. Chairman of the Indonesian Farmers Federation.

B. DUTY OF THE BFSC

The duty of the BFSC is as follows:

1. To develop the policy and assessment procedure of biosafety, food safety, and monitoring of Genetically Engineered Agricultural Products (GEAPs);
2. To issue some advice and technical consideration about biosafety and food safety for the utilization of GEAPs;
3. To carry out the technical assessment on the application of biosafety and food safety for the utilization of GEAPs;
4. To recommend a GEAP as safe or not safe as one of the considerations for the utilization of a GEAP;
5. To give advice in the management and control in the case of the utilization of a GEAP that causes biosafety and food safety harm;
6. To develop collaboration and consultation among various domestic institutions and foreign countries in biosafety and food safety of GEAPs;
7. To prepare relevant information about the implementation of biosafety and food safety for the utilization of GEAPs**;**
8. To evaluate and assess biosafety and food safety due to the utilization of GEAPs.

C. RESPONSIBILITY OF THE BFSC

The responsibility of the BFSC is as follows:

1. To evaluate a report on the technical assessment results of biosafety and food safety of the GEAP from the Biosafety and Food Safety Technical Team (BFSTT);
2. To safely keep the confidentiality and secrecy of the documents which relate to the technical and trade aspects in the assessment application of biosafety and food safety of a GEAP;
3. To report the implementation of their duty and responsibility to the Minister of Agriculture, Minister of Forestry and Estate Crops, Minister of Health, and State Minister of Food and Horticulture in line with the authority of each Minister at least once a year.

D. OTHERS

1. In implementing their duty, the BFSC is assisted by the BFSTT, while their membership, duty, and responsibility is determined by the Joint Decree of the Director General of the Agency for Agricultural Research and Development, Director General of the Agency for Forestry and Estate Crops Research and Development, Director General of Food and Drug Inspection, and Assistant of the State Minister of Food and Horticulture Division on Quality and Food Safety.
2. All expenses required in the implementation of BFSTT's are born by the Department of Agriculture, Department of Forestry and Estate Crops, Department of Health, and the State Ministry of Food and Horticulture in line with the authority of each Minister.

Annex VII

Information needed for application of LMOs

I. Transgenic Animals, Materials Originating from Them and Their Processed Products

Assessment of biosafety and food safety of transgenic animals, materials originating from them, and their processed products must fulfill the following requirements:

a. the genus name, species, and the animal line;
b. the modification methods used in the process of engineering transgenic animals;
c. when a vector is used in the genetic modification, the vector used must not be a pathogen organism either for human beings or other organisms;
d. complete information on the source of the genes used and the method of destruction of the remaining vector;
e. the genetic modification attempts carried out will not cause a change in animal behavior;
f. information on the phenotypic modification as a result of genetic engineering will not cause improper side effect (for example an unproportional physical form);
g. information concerning the reproduction performance of transgenic animal (fertile or infertile) needs to be elucidated. In case the transgenic animal is fertile, the presence of similar animal, especially those having close genetic relationships capable of cross breeding (including parents) must be explained;
h. information on the method of eradication in case of the unwanted deviation;
i. the kind of feed, ability to feed, and the manner of feeding.

I.2. Additional informations for transgenic animals used for food and feed stuff, and industrial raw materials

a. stability of insert gene and gene efficacy;
b. nutritional quality/value;
c. natural or modified toxic compound, anti nutrition and allergen;

d. to fulfill the requirements of substantially equivalent;
e. generally regarded as safe to be consumed;
f. molecular characterization and stability of genetic modification carried out;
g. expression, function and effect of genetic modification;
h. possible change on ecosystem of soil, water, and biological resources that might take place.

I.3. Additional information for transgenic pet animal used for hobbies and sports

a. stability of insert gene and gene efficacy;
b. natural or modified toxic compound, anti nutrition and allergen;
c. molecular characterization and stability of genetic modification carried out;
d. expression, function and effect of genetic modification;
e. possible change on ecosystem of soil, water, and biological resources that might take place.

I.4. Additional information for transgenic laboratory animals used for experiment, scientific and technological tool, and for disease control,

a. stability of insert gene and gene efficacy;
b. targeted organism;
c. expression, function and effect of genetic modification;
d. possible change on ecosystem of soil, water, and biological resources that might take place.

I.5. Additional information for transgenic animals used for food and feed stuff, industrial raw material, must also be accompanied by the following information:

a. stability of insert gene and gene efficacy;
b. nutritional quality/value;
c. natural or modified toxic compound, anti nutrition and allergen;
d. to fulfill the requirements of substantially equivalent;
e. generally regarded as safe to be consumed;
f. molecular characterization and stability of genetic modification carried out;
g. expression, function and effect of genetic modification.

6. Processed products of transgenic animals.

a. nutritional quality/value;
b. natural or modified toxic compound, anti nutrition and allergen;
c. to fulfill the requirements of substantially equivalent;
d. generally regarded as safe to be consumed.

II. Information requirement of Transgenic Fish, Materials Originating from Them and Their Processed Products

II.1. Basic Information

a. the name, genus, and species of fish;
b. the modification methods used in the process of engineering transgenic fish;
c. when a vector is used in the genetic modification, the vector used must not be a pathogen organism either for human beings or other organisms;
d. complete information on the source of the genes used and the method of destruction of the remaining vector;
e. information on the phenotypic modification as a result of genetic engineering will not cause improper side effect (for example an unproportional physical form);
f. the genetic modification attempts carried out will not cause a change in fish behavior;
g. information concerning the reproduction performance of transgenic fish (fertile or infertile) need to be elucidated. In case the transgenic fish is fertile, the presence of similar fish, especially those having close genetic relationships capable of cross breeding (including parents) with transgenic fish must be explained;
h. information on the method of eradication in case of the unwanted deviation;
i. the kind of feed, and the manner of feeding.

II.2. Additional information for transgenic fish used for food and feed stuff, and industrial raw material.

a. stability of insert gene and gene efficacy;
b. nutritional quality/value;
c. natural or modified toxic compound, anti nutrition and allergen;
d. to fulfill the requirements of substantially equivalent;
e. generally regarded as safe to be consumed;
f. molecular characterization and stability of genetic modification carried out;
g. expression, function and effect of genetic modification;
h. possible change on ecosystem of soil, water, and biological resources that might take place.

II.3. Additional information for transgenic pet fish used for as hobby, handicraft, decoration, and other need,

a. stability of insert gene and gene efficacy;
b. natural or modified toxic compound, anti nutrition and allergen;
c. molecular characterization and stability of genetic modification carried out;
d. expression, function and effect of genetic modification;
e. possible change on ecosystem of soil, water, and biological resources that might take place.

II.4. Additional information for transgenic laboratory fish used for disease control tools, and science:

e. stability of insert gene and gene efficacy;
f. targeted organism;
g. expression, function and effect of genetic modification;
h. possible change on ecosystem of soil, water, and biological resources that might take place.

II.5. Additional information for materials originating from transgenic fish used for food and feed stuff, industrial raw material.

h. stability of insert gene and gene efficacy;
i. nutritional quality/value;
j. natural or modified toxic compound, anti nutrition and allergen;
k. to fulfill the requirements of substantially equivalent;
l. generally regarded as safe to be consumed;

m. molecular characterization and stability of genetic modification carried out;
n. expression, function and effect of genetic modification.

II.6. Additional information for processed products of transgenic fish used for food and feed stuff:

e. nutritional quality/value;
f. natural or modified toxic compound, anti nutrition and allergen;
g. to fulfill the requirements of substantially equivalent;
h. generally regarded as safe to be consumed.

III. Information required for Transgenic Plants, Their Parts, and Their Processed Products

III.1. Basic information for assessment of biosafety and food safety of transgenic plants, their parts, and their processed products:

a. the genus name, species, cultivar of its species;
b. the modification methods used in the process of engineering transgenic plants;
c. when a vector is used in the genetic modification, the vector used must not be a pathogen organism either for human beings or other organisms;
d. complete information on the source of the genes used and the method of destruction of the remaining vector;
e. reproduction systems of its parents;
f. new genetic trait inserted into the transgenic plant;
g. information on the presence of wild relatives of the parents species;
h. method of eradication in case of the unwanted deviation.

III.2. Additional information for transgenic plants used for food and feed stuff.

a. stability of insert gene and gene efficacy;
b. nutritional quality/value;
c. natural or modified toxic compound, anti nutrition and allergen;

d. to fulfill the requirements of substantially equivalent;
e. generally regarded as safe to be consumed;
f. possibility of cross breeding with wild relative;
g. possibility of the development of resistance to plant pests or herbicide of non target species through out-crossing;
h. expression, function and effect of genetic modification.

III.3. Additional information for transgenic plants and their processed products used for medical ingredients, must also be accompanied by the following information:

a. stability of insert gene and gene efficacy;
b. molecular characterization and stability of genetic modification carried out;
c. certain chemical ingredient including the possible efficacy and side effects (toxicity);
d. natural or modified toxic compound, anti nutrition and allergen;
e. to fulfill the requirements of substantially equivalent;
f. generally regarded as safe to be consumed;
g. possibility of cross breeding with wild relative;
h. possibility of the development of resistance to plant pests or herbicide of non target species through out-crossing.

III.4. Additional information for transgenic plants used for biological control :

a. possibility of insert possessing invasive characteristics;
b. targeted organisms;
c. possibility of cross breeding with wild relative;
d. molecular characterization and stability of genetic modification carried out;
e. possible change on ecosystem of soil, water, and biological resources that might take place.

III.5. Additional information for transgenic plants used for bio-fertilizer and bio-remediation:

a. stability of insert gene and gene efficacy;
b. targeted organisms;

c. possibility of cross breeding with wild relative;
d. molecular characterization and stability of genetic modification carried out;
e. possible change on ecosystem of soil, water, and biological resources that might take place.

III.6. Additional information for transgenic plants used for industrial raw materials:

a. stability of insert gene and gene efficacy;
b. natural or modified toxic compound, anti nutrition and allergen;
c. possibility of cross breeding with wild relative;
d. molecular characterization and stability of genetic modification carried out;
e. possible change on ecosystem of soil, water, and biological resources that might take place.

III.7. Additional information for transgenic plants used for ornamental plants:

a. stability of insert gene and gene efficacy;
b. natural or modified toxic compound, anti nutrition and allergen;
c. possibility of cross breeding with wild relative;
d. molecular characterization and stability of genetic modification carried out;
e. possible change on ecosystem of soil, water, and biological resources that might take place.

III.8. Additional information for processed products of transgenic plants :

a. nutritional quality/value;
b. natural or modified toxic compound, anti nutrition and allergen;
c. to fulfill the requirements of substantially equivalent;
d. generally regarded as safe to be consumed.

IV. Information requirement of Transgenic Microorganisms

IV.1. Basic informations for biosafety and food safety of transgenic microorganisms:

a. genus and origin of parent microorganism, microorganisms source of insert, and microorganisms source of vector;
b. the modification methods used in the process of engineering transgenic microorganisms;
c. when a vector is used in the genetic modification, the vector used must not be a pathogen organism either for human beings or other organisms;
d. presence of wild relative of parents microorganism as well as microorganisms source of vector;
e. method of eradication in case of the unwanted deviation;
f. complete information on the source of the genes used and the method of destruction of the remaining vector;
g. information on the method of eradication in case of the unwanted deviation.

IV.2. Additional informations for transgenic microorganisms used for industrial process for food and feed :

a. stability of insert gene and gene efficacy;
b. material for production process produced;
c. kind of food, method of processing before consumption, and the quality of food after processing; and/or
d. natural or modified ingredients of toxic compound, anti nutrition, and allergen;
e. to fulfill the requirements of substantially equivalent;
f. generally regarded as safe to be consumed;
g. molecular characterization and stability of genetic modification carried out.

IV.3. Additional information for transgenic microorganisms used for food and feed:

a. stability of insert gene and gene efficacy;
b. kind of feed or material, method of processing and the quality of material after processing; and/or

c. kind of food, method of processing before consumption, and the quality of food after processing;
d. natural or modified ingredients of toxic compound, anti nutrition, and allergen;
e. to fulfill the requirements of substantially equivalent;
f. generally regarded as safe to be consumed;
g. molecular characterization and stability of genetic modification carried out.

IV.4. Additional information for transgenic microorganisms used for fertilizer, pesticide, and other production inputs:

a. stability of insert gene and gene efficacy;
b. mechanism of microbe activities as production inputs;
c. natural or modified ingredients of toxic compound, anti nutrition, and allergen;
d. molecular characterization and stability of genetic modification carried out;
e. information on targeted plants.

IV.5. Additional information for transgenic microorganisms used for processing of side products and/or agricultural waste as well as for bioremediation inputs

a.stability of insert gene and gene efficacy;
b.type and mechanism of microbe activities and the nature of the side products including the liquid, solid and gas physical characteristics;
c. molecular characterization and stability of genetic modification carried out;
d. possible change on ecosystem of soil, water, and biological resources that might take place.

IV.5. Additional information for transgenic microorganisms used for animal vaccine and concealed vaccine:

a. type of vaccine (active or inactive);
b. kind of vaccine (polyvalent or monovalent);
c. persistence of the active vaccine in the vaccinated of or after excreted from the organism body;

d. possibility of active vaccine mutation resulting in vaccine teratogenic effects.

IV.6. Additional information for transgenic microorganisms used for antisera, probiotic, and biological material:

a. microorganism line used;
b. physiological characteristics of the line;
c. direct and indirect effect on the environment;
d. pre-clinical and clinical problems;
e. impacts of the administration of antisera, probiotic, and biological material which is administered to livestock on human beings.

Annex VIII

MODEL A

Application Letter for
the Assessment of Biosafety and Food Safety of
Genetically Engineered Agricultural Products

Number	:			
Attachment	:			
Subject	:	Application for the Assessment of Biosafety and Food Safety of Genetically Engineered Agricultural Products		To Related Director General

We herewith:

1.	Name of Company/Agency/Individual *)	:
2.	Deed of Establishment/Legal Legality (enclosed)*)	:
3.	Taxpayer Identification Number (NPWP) enclosed	:
4.	Name of the Manager/Person Responsible:	:
5.	Address of the Office of the Company/Agency/ Individual	:
6.	Code Number of the Company/Agency/Individual (if any)	:

We are submitting an application for the Assessment of Biosafety and Food Safety of a Genetically Engineered Agricultural Product.

As the material for your consideration, we have enclosed data and documents concerning the answers to the necessary questions, to complete the application referred to.

Please be informed accordingly and we thank you for your approval.

Name and Signature
Manager/Person Responsible

……

cc to:
Biosafety and Food Safety Committee
*) delete the inapplicable

Annex IX

QUESTIONS FOR THE APPLICANT/BACK UP INFORMATION

(1) The Applicant for the utilization of a genetically engineered agricultural product must answer the core questions that are mentioned in Section A and the other relevant Sections of the Application.

(2) It is the obligation of those who are involved in the compilation of an Application to give an overall consideration to the Department of Agriculture, Department of Forestry and Estate Crops, Department of Health, and State Ministry of Food And Horticulture on the impact that may take place as the result of the utilization proposed, and complete information concerning the relevant matters. The impact that needs to be paid attention to includes the influence on safety and health of the community, agricultural production, other living creatures and environmental quality. Attention must be given to the experience of research on the same genetically engineered agricultural products in a closed place.

(3) Answers should be supported with data and the appropriate references. If the supporting data is not available, the basis of the answer should be explained. In case of any doubt in giving the correct answer to a question, the nature of doubt must be explained. If it is estimated that there is a potential danger, clear and complete information concerning the existing risks must be given, and if possible, various steps which may be used to prevent and control the risks, must be considered and suggested.

A. CORE QUESTIONS

Species to be released

A1 What species name of Genetically Engineered Agricultural Product is to be released? In case of being relevant, give some information concerning strain, cultivar, pollution and so on.

A2 Would such Genetically Engineered Agricultural Product cause illnesses or disturbance to the health of human beings, plants or animals? If yes,

what effects may occur?

A3 (i) Where did the exogenous genetic material come from? Give information clearly.

(ii) Did such genetic material come from an organism that may cause illnesses or harm the health of human beings, plants, or animals? If yes, how would the effect possibly occur?

Special purposes of the utilization

A4	(i) What are the objectives of the application and the ultimate utilization of the Genetically Engineered Agricultural Product?
	(ii) What are the benefits of the chosen method in comparison to other methods?

Location

A5 Clarify how many Genetically Engineered Agricultural Products are to be released, and when relevant, the extent of land to be used, and where the location is. When relevant draw the map.

A6 (i) What are the reasons for choosing such location?

(ii) Clarify in details the relevant nature of the physical environment, particularly those which may cause undesired consequences.

(iii) How far is the location of the utilization from the residential area, center of agricultural activities, or the habitat of the Genetically Engineered Agricultural Products which may have an effect or be affected?

Habitat and ecology

A7 (i) What is the natural habitat of the said genetically engineered agricultural products, and what is the extent of its scope?

(ii) Where were the parents of such genetically engineered agricultural products discovered for the first time?

(iii) How is the dispersal of the parents in Indonesia?

(iv) Are the parents already in existence at or adjacent to the location of the planned utilization? If yes, give the data pertaining to their populations.

(v) Are the parents of the genetically engineered agricultural products foreign to Indonesia?

A8 Are there other organisms in Indonesia acting as predator or parasites against the genetically engineered agricultural products, which are to be released?

A9 Would the utilization of genetically engineered agricultural products disrupt the function of the parent which is useful to the environment?

A10 Clarify each ecological effect, directly or indirectly, that may be anticipated as a consequence of the utilization, which is not covered by the questions in the following section (B, C, D, and so on).

The genetics of genetically engineered agricultural products

A11 What genetic traits have been engineered? Clarify in details about the steps that have been taken.

A12 Would the genetically engineered agricultural products genotypically have the opportunity of becoming unstable?

A13 (i) How far has the genetic modification been characterized? Give the data

(ii) At what location has the DNA been inserted and how many copies are available?

(iii) What marker or sequence may be used to identify the genetically engineered agricultural products at the laboratory or in the field?

A14 (i) What types of vectors are used to carry out the transformation? Clarify such vectors, position of the inserted DNA and the sequence control or marker within the vector.

(ii) Can the vector be transferred to another host? If yes, give the data

about the dispersal of the host of vector

(iii) Is the recombinant vector still being found in the genetically engineered agricultural products? If not, how to remove such recombinant vector?

A15 In case no vector is used:

(i) if exogenous nucleic acid exists in the genetically engineered agricultural products, how were they inserted?

(ii) How many copies of the genes are inserted?

(iii) What genetic side effects are to be anticipated?

A16 How does the genetic modification change the phenotype of the genetically engineered agricultural products which will be released? Give the data to show the effect of modification, including the level of expression and regulation of the inserted gene

A17 (i) If any, which intrinsic genetic trait of the genetically engineered agricultural products could control its persistence and dispersion in nature? How stable are these traits?

(ii) What genetic changes, if any, have been done on the genetically engineered agricultural products to limit or to lose its ability to reproduce or to transfer its gene to other genetically engineered agricultural products?

Contained experimental data and other research pertaining to the stability, persistence, dispersion and movement

A18 Based on contained experiment or other relevant experience, give the data pertaining to:

(i) the persistence of genetically engineered agricultural products in the planned habitat of utilization;

(ii) parental growth rate and the genetically engineered agricultural products in the secured environment and period of utilization

(iii) the frequency of reversion or losing the genetically modified traits

A19 (i) How is the spreading capability of the genetically engineered agricultural products from the place of utilization? How is the dispersal mechanism: through the air, water or ground?

(ii) Can the parent create a structure to survive for a long period such as seeds or spores?

A20 Is there any evidence of the possibility of the released traits to be transferred to the other existing organisms in the area of utilization? If yes,

(i) into what organism and what are the frequencies? Give a list of the species tested or evaluated on its ability to receive those characteristics, and clarify the reason for having chosen them

(ii) How about its transfer mechanism?

(iii) What technique is used to indicate the ability of receiving the characteristics or its transfer?

(iv) What is the adverse effect as a consequence of the transfer of such characteristics?

A21 Do the modified characteristics provide selective benefit to the genetically engineered agricultural products? If yes, under what condition? Give data concerning growth rate with or without the selection pressure

A22 Do you expect that the genetically engineered agricultural products could give a competitive benefit as compared to its unmodified parent in a mix population at the testing place? If yes, what are the benefits?

Experimental procedure, monitoring and emergency planning

A23 (i) Clarify in detail the protocol of utilization trial, the protocol of control, and testing of the genetically engineered agricultural products

(ii) How many genetically engineered agricultural products are planned to be released?

(iii) How many genetically engineered agricultural products are proposed to be released?

A24 (i) What plans have been made to multiply the genetically engineered agricultural products in a large number and its transfer to the place of the experiment?

(ii) How will the genetically engineered agricultural products be released?

A25 (iii) What method will be applied to test the inter batch variability in case the genetically engineered agricultural products are needed in large quantity?

(iv) What special precaution has been or will be taken in the production process to ensure the quality/purity achievement of the genetically engineered agricultural products?

A26 (i) How to monitor the persistence of the genetically engineered agricultural products? Give a clarification concerning the technique of monitoring the presence and movement of the genetically engineered agricultural products or genetic material from the testing place, including specificity, sensitivity and reliability of the method of its detection

(ii) In case the utilization would influence the characteristics or quantity of other species, how is the method of monitoring?

(iii) How to monitor the gene transfer to other species?

A27 (i) If any, what potential hazard and harmful effect could be suspected and how could that possibility be evaluated during the utilization process?

(ii) Explain each procedure applied to test the spreading of genetically engineered agricultural products.

(iii) Should the gene transfer resulted in the adverse consequence (see question A20), what methods could be applied to minimize the consequences?

A28 (i) Will the genetically engineered agricultural products persist in the environment after the utilization trial has been completed? If yes, (a) for how long, and (b) what will be the consequence?

(ii) Are there steps to reduce the population or to eliminate the genetically engineered agricultural products after they have been released? If yes, give the details.

(iii) What monitoring could be done after the trial has been completed?

A29 What measures could be taken to eliminate the genetically engineered agricultural products in case the danger arises during the utilization trial?

A30 Explain all procedures of supervision and safeguarding to be done by the executors.

A31 Explain the method of disposing of any used materials.

Other evaluation methods

A32 Has the BFSC ever evaluated an application to develop a small-scale test of the genetically engineered agricultural products? If yes, what are the results?

A33 (i) Has the same or similar utilization ever been carried out before, either inside or outside of Indonesia? If yes, what were the beneficial and harmful consequences? Give references or report on those previous evaluations.

(ii) Is there any country that has denied the application for the utilization of the genetically engineered agricultural products? If yes, what is the basis of such denial?

(iii) What factors would possibly cause a serious/less serious risk in the utilization proposed in Indonesia when compared to the utilization proposed abroad?

A34 Are the genetically engineered agricultural products imported? If yes, give the documentation concerning the licensing or evaluation of the quarantine

A35 Are there reasons to suspect that in case such genetically engineered agricultural products are released, they would cause a danger which is not mentioned in the application, (a) at the region of destination, or (b) at another region in Indonesia? If yes, explain it.

B. PLANTS

In case the plants are intended for food or fodder, answer also questions included in section J.

B1 Has the parent plant had an extended history of cultivation and safe use? If not, explain it.

B2 If any, what unintended pleiotropic effects, including undesirable effects on the agronomic traits, may result from transgene expression in the genetically engineered agricultural products (e.g. reduced fertility, increased disease prevalence, loss of production, grain shattering). Indicate the likelihood of these events.

B3 (i) Describe the mechanisms of pollen spread of the plants (by insect vectors or by other means).

(ii) Provide the data on pollen viability of the plant.

(iii) Indicate potential pollinators and their distribution in Indonesia.

B4 (i) Is there any unmodified plant belonging to the same genus known as a weed? If so, specify.

(ii) Is there any literature report on cross-pollination between plant species similar to the genetically engineered agricultural products with its wild species known as weeds? If so, please list.

B5 (i) Provide quantitative data of the successful cross-pollination between such plant and its wild species.

(ii) If you know any plant which is sexually compatible with the genetically engineered agricultural products in the area of intended release, give the details and quantify the chances cross-pollination.

(iii) If such cross-pollination took place can the offspring survive? If not, why?

B6 (i) Will the released plant be allowed to set seeds? If not, is that planned for the next utilization?

(ii) If the plant is allowed to set the seeds, is the mature seed normally remain contained within an ear, capsule, pod etc. so that practically all of the seeds can readily be harvested, or is the seed shed soon after it matures?

(iii) Can the seed be dispersed by natural mechanisms? If so, describe.

(iv) Are the seeds capable of being dormant for a long tome? If so, for how long?

B7 Can the plant be dispersed by vegetative propagation? If so, describe the possible mechanisms.

B8 (i) What is the likelihood that the inserted characteristic could be transferred into other species, with adverse consequences?

(ii) If there is any possibility of such transfer, would it have the potential to affect the distribution and abundance of the other species? If so, specify.

(iii) If there is any possibility of such transfer, has any attempt been made to minimize the risk (e.g. by inserting male sterility or other means of reproductive isolation)? If not, why?

B9 How might the plant's competitive advantage (fitness) be changed (i) in the agricultural setting, (ii) in the natural environment? Explain.

B10 Does the new characteristic change the capacity of the plant to add substances to or subtract substances from the soil (e.g. nitrogen, toxic compounds)? If so, describe the change.

B11 (i) Is there any possibility that the inserted gene could cause an increase in toxicity of the plant for animal and humans? If so, provide available data.

(ii) Could any products of the plant concentrate in the natural or human food chain to levels which become toxic? If so, explain.

(iii) Is the biodegradability of the plant changed? If so, how?

B12 What the secondary ecological effects might result from release of the genetically engineered agricultural products (e.g. effect on endangered native species, resistance of insect populations to an insecticide, reduction or increases in numbers of prey or parasites, etc.)?

B13 If the genetically engineered agricultural products contain resistance to a chemical agent (other than selective agents, such as antibiotics, used in strain construction):

(i) provide data on degradability, selectivity and toxicity of the chemical concerned;

(ii) What is the agronomic significance of the chemical?

(iii) What is the biological activity of the chemical?

(iv) How is the chemical applied and used?

B14 If the genetically engineered agricultural products contain resistance to herbicide, explain whether:

(i) The release will result in more effective use of herbicide?

(ii) The release will result in better weed control in the crop?

(iii) The release will result in a more efficient overall farming operation?

(iv) The release will allow a change to a program which involves environmentally friendly chemical or practices?

C. MICROORGANISMS LIVING INSIDE OR ON THE SURFACE OF ANIMAL

Question here relate to genetically engineered agricultural products such as microorganisms within the digestive tract living within a larger host and microorganisms applied on the surface of animals.

C1 What is the animal host species?

C2 Does the parent organism have an extended history of use in agriculture? If so, please elaborate.

C3 Is there any evidence that the genetically engineered agricultural products capable of surviving in or on other animals, including feral animals? If so, what are those animals and what are the effects?

C4 (i) What new capacity will the genetically engineered agricultural products provide for the host species? (e.g. ability to degrade plant or pasture toxin)?

(ii) What secondary effects can be postulated from conferring that capacity on the host?

C5 Will the competitive advantage or ecological fitness of the host be altered? Explain, providing data to support your answer.

C6 What effects (including secondary effects) are likely on other plants or animals in the agricultural and natural environments? (Please include in your answer any possible effect on non-host animals or feral populations).

C7 What secondary effects could be postulated from the introduction of the genetically engineered agricultural products into or onto the host? (For

example, is there a possibility of the genetic insert being transferred to other organisms in the host, or to host cells?)

C8 For genetically engineered agricultural products living in animals, will the genetically engineered agricultural products be excreted or otherwise leave the animal? If so, for how long does it survive outside the animal?

C9 (i) What is the survival and dispersal of the genetically engineered agricultural products in natural waters and soil?

(ii) What could be the effects of the genetically engineered agricultural products on water quality?

(iii) Do the genetically engineered agricultural products produce spores?

(iv) Are the genetically engineered agricultural products resistant to desiccation?

C10 (i) What sterilizing and anti-microbial agents are active against the genetically engineered agricultural products?

(ii) Are the genetically engineered agricultural products susceptible to UV and ionizing radiation?

D. MICROORGANISMS NOT FALLING INTO SECTIONS C

Questions here relate to microorganisms associated with plants and microorganisms which might be applied to modify the physical or chemical environment (e.g. microorganisms to modify soil properties).

D1 For microorganisms associated with plants, what is the partner species of plant? Describe the specificity of the interaction and indicate the range of plant species with which the genetically engineered agricultural products can interact.

D2 Has the parent organism an extended history of use in agriculture? If so, please elaborate.

D3 For microorganisms associated with plants:

(i) What is the effect of the genetically engineered agricultural products on the partner plant species and how will this be monitored?

(ii) What other secondary effects might the genetically engineered agricultural products have on the plant?

(iii) Does the modification cause any change to the range of host plant species available to the organism?

(iv) What effect of the genetically engineered agricultural products, if any, is anticipated on the distribution and abundance of the host plant species and other species with which the organism can interact?

D4 If the genetically engineered agricultural products are associated with plant species which are food crops, could it affect the suitability of the resultant produce for human or animal consumption? If so, explain.

D5 What are the effects expected on soil chemistry (e.g. pH, mineral leaching, chelation, nutrient levels)?

D6 (i) What is the survival and dispersal of the genetically engineered agricultural products in natural waters and soil?

(ii) What are any possible/likely effects of the genetically engineered agricultural products on water quality?

(iii) Do the genetically engineered agricultural products produce spores?

(iv) Are the genetically engineered agricultural products resistant to desiccation?

D7 What effects might the genetically engineered agricultural products have on soil organisms which are known to be beneficial to plants (e.g. *Rhizobium*, *Azospirillum*, *Frankia* and mycorrhizal fungi) and are likely to be in the test area?

D8 What is known about interactions between the genetically engineered agricultural products and closely related microorganisms in the partner plant (if applicable) or the environment of the site of introduction?

D9 For genetically engineered agricultural products associated with plants, what effect they might have on insects, birds and animals (including humans) which may eat the plant?

D10 Do the genetically engineered agricultural products exchange genetic material with known plant pathogens? If so, elaborate.

D11 (i) What sterilizing and anti-microbial agents are active against the genetically engineered agricultural products?

(ii) Are the genetically engineered agricultural products susceptible to UV and ionizing radiation?

E. VERTEBRATES, NOT INCLUDING FISH

If transgenic animals are to be consumed as a food, answer also the questions in Section J.

Questions here relate to all animals except fish. Please note that all work involving animals should be conducted according to widely accepted principles for the safe and humane treatment of experimental animals.

E1 (i) What unintended effects (to the environment, animal welfare) may result from the planned introduction, and what is their likelihood?

(ii) Are any of the intended gains directly linked to changes in other characteristics of the species? If so, specify.

E2 What effects might the expression of the modified trait have on the physiology, behavior and reproduction of the animal? Explain, with data (e.g. studies from model animals).

E3 Will the animals in this experiment be allowed to breed? If not, is breeding planned for later experiments or in the commercial phase?

Are the arrangements for handling any offspring the same as those for the experimental animals? If not, please specify the arrangements.

E4 (i) Does the embryo, or product of the genetically engineered animal contain recombinant DNA expressed using the viral expression system?

(ii) If so, with reference to question E4 (i) above, what viral strain was the vector of the recombinant DNA?

(iii) In relation to question E4 (ii), please refer to question K1 (iii).

E5 (i) What new genetic materials were inserted into the embryo (pro-nucleus stage)?

(ii) What kind of product is expected from adult transgenic animal (at the proper age)?

(iii) Is the transgenic animal and/or product of it expected for humans consumption?

(iv) What the likelihood that these products will be dangerous to human beings and animals consuming these products? If so, explain.

E6 (i) Is the transgenic animal fertile and capable of mating with its parents?

(ii) Could the recombinant DNA used to develop the transgenic animal be integrated to the genome of non-transgenic animal (existing in Indonesia) through mating?

(iii) If so, what was the vector of the recombinant DNA?

(iv) In relation to question E6 (ii), please refer to question K1 (iii).

E7 (i) Is the new genetic material inserted into the embryo isolated from a human gene encoding a certain useful protein?

(ii) Will the protein produced by the transgenic animal be used for medical treatment? If so, please refer to the provisions on the medical application concerned.

(iii) In testing of the protein, please refer to question K10.

E8 What management procedures and environmental factors, if any, are required for optimal expression of the introduced trait? Provide data to support your answer.

F FISH AND OTHER AQUATIC ORGANISMS

If the genetically engineered agricultural products are to be consumed as a food, answer also the questions in Section J.

F1 (i) Could the genetically engineered agricultural products produce any 'new' metabolites or toxins likely to have deleterious effects on parasites or predators? If so, elaborate.

(ii) What other unintended effects may result from the planned introduction? Your answer should include consideration of the effect of the genetically engineered agricultural products on the community ecology at the site of the planned introduction.

(iii) Are any of the likely gains directly linked to losses in other characteristics of the genetically engineered agricultural products?

F2 (i) Will the genetically engineered agricultural products in this introduction be allowed to breed? If not, is breeding planned for later introductions or commercial use?

(ii) Are the arrangements for handling any offspring the same as those for the experimental organisms? If not, please specify the arrangements.

F3 Can the changed or added DNA be transmitted by means other than by reproduction normal for the species or to any other species? If so, specify, and elaborate its effects.

F4 Do natural populations of the parental organism exist in Indonesia (including in rivers, lakes, or coastal waters)? If so, do the natural populations cause problems to other genetically engineered agricultural products? Specify the kinds of genetically engineered agricultural products and the problems.

F5 If natural populations of the genetically engineered agricultural products to be modified exist in Indonesia, could the modified characteristics enhance the ability of the species to establish populations in aquatic habitats?

F6 Has any experimental work been done on phenotypic expression of the introduced genetic material in naturally occurring genetically engineered agricultural products (e.g. cross-breeding of genetically engineered agricultural products with wild/farmed stocks)? If so, what were the results?

F7 What is the likelihood of the introduced genetic material entering the gene pool of natural populations?

F8 Could the entry of the introduced genetic material into the gene pool of a natural relative to the genetically engineered agricultural product have any effect on the distribution and abundance of the genetically engineered agricultural products or on associated fisheries, the environment or public health? If so, please explain.

F9 What mechanisms will be used to prevent dispersal of the genetically engineered agricultural products into other ecosystems?

G. INVERTEBRATES

If the genetically engineered agricultural product is to be consumed as a food, answer also the questions in Section J.

G1 (i) What effects might the genetically engineered agricultural products have on the food chain?

(ii) Could the genetically engineered agricultural products produce any 'new' metabolites or toxins likely to have deleterious effects on parasites or predators? If so, elaborate.

(iii) What other unintended effects may result from the introduction? Your answer should include consideration of the effect of the genetically engineered agricultural products on the community ecology at the introduction site.

G2 (i) Will the genetically engineered agricultural products in this introduction be fertile? If not, is it intended to use fertile organisms in later introductions?

(ii) Are the genotype and phenotype of the offspring the same as those of the genetically engineered agricultural products to be introduced? If not, please specify the differences.

G3 Do populations of the parental organism exist in Indonesia? If so, do these populations cause agricultural, environmental or public health problems or benefits? Specify the problems or benefits.

G4 (i) Can the changed or added genetic material be transmitted by means other than reproduction normal for the species? If so, specify, and elaborate its effects.

(ii) What is the likelihood of the introduced genetic material entering gene pools of natural populations?

(iii) Can the changed or added genetic material be transmitted to any

other species? If so, specify the mechanism of transfer and list the species.

G5 Has any experimental work been done on the phenotypic expression of the introduced genetic material in other genetic backgrounds (e.g. cross-breeding of modified strains with wild/caught stock)? If so, what were the results?

G6 Could the gene of the genetically engineered agricultural products have any effect on the structure of the natural populations? What would be the effect of this change?

G7 What mechanisms will be used to prevent dispersal of the genetically engineered agricultural products into other ecosystems?

H. ORGANISMS FOR BIOLOGICAL CONTROL

H1 (i) What is the species targeted for biological control?

(ii) What direct effects does the parent organism have on the target species?

(iii) What direct effects does the genetically engineered agricultural product have on the target species?

H2 (i) What is the host range of the genetically engineered agricultural products? If the host range of the genetically engineered agricultural products is likely to be different from that of the parent organism, explain why.

(ii) What non-target organisms have been tested for susceptibility to the genetically engineered agricultural products?

(iii) What is the rationale for the choice of species tested?

H3 Does the genetically engineered agricultural product have a mechanism of self-elimination (e.g., infertility) that will limit its persistence in the

environment? If not, please refer to question G7.

H4 How are the genetically engineered agricultural products transferred from one target individual to another and what factors affect this transferability?

H5 What secondary effects can be envisaged on predators, prey or parasites of the target species?

H6 (i) Explain the consequence of the removal or reduction of the target species on the management of agriculturally significant plants or farm animals.

(ii) Predict any change in the ecosystem resulting from a reduction in the population of the target genetically engineered agricultural products.

H7 Does the genetically engineered agricultural product produce metabolites which may have deleterious effects directly on other genetically engineered agricultural products or indirectly through concentration in the food chain? If so, elaborate.

H8 Can the modified genetic traits be transmitted to other genetically engineered agricultural products which are likely to be in the environment (see A20), are these other genetically engineered agricultural products likely to affect non-target species?

H9 What genetic response might be invoked in populations of the target organism as a result of the use of the genetically engineered agricultural products (e.g. increased resistance to the genetically engineered agricultural products)? What evidence is there for this response?

I. ORGANISMS FOR BIOREMEDIATION

I1 (i) What is the target substrate for bioremediation?

(ii) What effect does the parent genetically engineered agricultural products have on the target substrate?

(iii) What effect does the genetically engineered agricultural product have on the target substrate?

I2 Describe natural strain variation of the parent organism that may be relevant to the assessment of the genetically engineered agricultural products.

I3 What other substances can be metabolized by the genetically engineered agricultural products which cannot be metabolized by the parent organism?

I4 Will the genetically engineered agricultural products be self-sufficient once exposed to the target substrate or will additional measures are required (e.g. provision of supplementary nutrients and growth factors or other environmental modifications)?

I5 Does the genetically engineered agricultural product produce metabolites which may have deleterious effects directly on other genetically engineered agricultural products or indirectly through concentration in the food chain? If so, specify.

I6 What effects might the genetically engineered agricultural products have on water, air or soil quality?

I7 What effects might the other genetically engineered agricultural products have on the genetically engineered agricultural product which ingests it?

I8 Will the genetically engineered agricultural products be dispersed from the site of application? If so, describe the mechanisms involved and the possible/probable consequences.

J. ORGANISMS TO BE CONSUMED AS FOOD

J1 Is the parent organism or the DNA donor already used in food production or eaten as food? If so:

(i) at what consumption levels, and

(ii) is any processing needed or commonly used before consumption?

J2 (i) Does the genetically engineered agricultural product produce metabolites which may have adverse effects on the consumer (humans or animals)? If so, elaborate. Provide available data on toxicology, allergenicity and other possible adverse effects.

(ii) Can any metabolite products of the genetically engineered agricultural products concentrate in the food chain to levels which may become toxic? If so, elaborate.

J3 Will the nutritional quality of the food be changed by the genetic modification? If so, how?

J4 Is the genetically engineered agricultural product to be processed during the production of the food? If so, elaborate.

K. MICROORGANISMS AS LIVE VACCINES FOR VETERINARY USE

K1 In general vaccines can be divided into two groups, namely the active (living) and inactive (dead or sub-unit) vaccines. Living vaccine contains not only several useful antigen but also several unimportant materials that constitutes a part of the vaccine which may cause undesirable side effects. Recombinant DNA vaccine may also contain only synthetic protective antigen.

(i) What kind of vector was used to develop the vaccines?

(ii) What vector strains were used?

(iii) State the physiological properties of the strains:

(a) the natural habitat;

(b) growth requirements;

(c) reproduction mechanism;

(d) level of persistence to environment;

(e) genetic information mechanism;

(f) pathogenicity and/or virulence.

K2 What kinds of genetically engineered agricultural products have been inserted by a recombinant vector? Refer to questions K1 (ii) and K1 (iii).

K3 Could the vector act as a vaccine? If so, refer to questions K1 (ii) and K1 (iii).

K4 (i) What are the reasons for using the vaccine?

(ii) What diseases are to be controlled by the vaccine?

(iii) What targeted pathogen would the vaccine be effective against?

(iv) Is the vaccine used an active vaccine? If so, answer questions K5, K6, K7, K8, K9, K10, K11, and K12 in detail.

K5 (i) Is the genetic material of the vector capable of integrating with the DNA of the vaccinated animal?

(ii) Can the genetic material of the vector be transferred to any other animal?

(iii) If the answer to questions (i) and (ii) is yes, please elaborate.

K6 (i) Can the genetically engineered active vaccine be found inside the vaccinated animals or within their feces or urine? If so, for how long after the vaccination was administered?

(ii) Is it possible that the genetically engineered active vaccine can contaminate unvaccinated animal or normal species? If so, explain the mechanism of such contamination.

K7 (i) How long will the immunity last after the vaccination?

(ii) What is the level (titer) of vaccine is expected to reach the desired level of immunity?

(iii) Is booster dosage required?

(iv) How many times should the entire vaccine be given?

(v) What is the purity level of the vaccine?

K8 (i) Is the vaccine capable of transforming back into its pathogenic form?

(ii) If the vaccine is injected to a pregnant animal, will the vaccine be transferred through the placenta?

(iii) If the vaccine is injected to a pregnant animal, will the vaccine cause pathologic effects to the fetus in every stage of pregnancy? If so, explain in detail.

K9 (i) Does the vaccine belong to polyvalent vaccine? If so, explain in detail (its nature and characteristics).

(ii) Can the vaccine be administered right before another vaccine without causing negative effect on its effectiveness?

(iii) Would the vaccine neutralize the use of other vaccines given afterwards?

K10 If an experiment has to be conducted to test its safety, elaborate the methods used for the disposal of waste and the vaccinated animal (especially animal carrying the active vaccine tested)

K11 If any, elaborate each method (chemical, physical and biological) to prevent the development or to eradicate the tested vaccine.

K12 If the vaccine is applied to zoonotic diseases, describe the susceptible animal, including their age group and the geographical distribution of the diseases.