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The Cost of Research and Development for Producing a Transgenic Crop and Its Biosafety Regulation Compliance in Indonesia

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Abstract: Since the last decade crop improvement using genetic engineering tools is one of the alternative approaches to increase and stabilise agricultural production in the world. However, producing a transgenic plant is a long and expensive process. Even after it led to the successful development of a plant with a desired trait, the transgene has to be followed up by a series of risk assessment stages required by the national biosafety commission. A risk assessment regulation process is required to assure the safety of food and feed and the environment and this latter activity is not costless. The objective of this study is to obtain the cost for research and development of selected transgenic crops engineered in Indonesia. In addition, we also investigated the cost of complying with the biosafety regulation. The result of our survey shows that it took 4-8 years to engineer a transgenic plant. Two of the samples' activities were started from gene isolation, and the rest were started from tissue culture and plant transformation using foreign genes. The R&D cost needed for each activity was around 1.3 billions IDR to 3.1 billions IDR (with Present Value of money (PV) equal to 2.3 billions IDR to 7.1 billions IDR). Those amounts were equivalent to US$154 thousands to US$522 thousands (US$274 thousands to 1.4 million PV). To comply with the regulation requirements for Bt-cotton, a multinational enterprise in Indonesia had paid around 919 millions IDR (974 millions IDR PV) equivalent to US$ 93 thousands (99 thousands US$ PV). These biosafety costs excluded the food/feed safety costs. Our survey also indicated that from 31 plant transformation activities, 16 are still on going, while the rest were either suspended or terminated. Of all 16 activities only two preceded into the regulation phase. Because producing a transgenic plant and complying with regulatory approval for commercial release are expensive and a long

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process, it is wise to set the research priorities based upon the country capacity and need. Research priorities should also based upon the estimation of the risk and benefit of all activities or stages. This includes the estimation of the fund needed starting from the initial activity to the last (release of the new variety).

Keywords: Biosafety regulations, Cost of biosafety, R&D, Transgenic crops, Risk assessment, Socio-economic assessment.

Background

Despite the ongoing debates between the opponents and proponents of transgenic plants, there is a substantial increase in cultivated area globally for transgenic crops. During the eight-year period 1996 to 2003, global areas increased forty fold from 1.7 million ha in 1996 to 67.7 million ha in 2003.[1] In 2005, the global approved GM crop was 90 million ha grown by 8.5 million farmers in 21 countries (10 industrial and 11 developing countries).[2]

Construction of transgenic plants was initiated in Indonesia in the mid 1990s. By then, there had been an increase in the number of Government and private institutions that performed research on transgenic plants. Along with the increasing number of institutions, the target plants and introduced traits have also become more numerous and have diversified.[3]

Due to the existing controversy on the benefits and risks of transgenic plants and their derivative products, the Indonesian government recognised the need for application of the technology with the "cautiousness" principle. This is reflected in various government regulations and decrees issued either by the President or by related Ministers. In 1996, the Government issued the first Law on transgenic plant which called "Undang-undang Pangan" no. 7/1996. In 1997, the Minister of Agriculture issued an SK No. 856Kpts/HK330/9/1997, a Ministerial Decree to regulate the biosafety of agricultural biotechnology products. This new Law/Decree was later revised in 1999 in a Joint Decree of the four Cabinet Ministers. Aside from biosafety, the new Decree had also made additional regulations on food safety. The Biosafety Commission was formed in 1997. These regulations on transgenic plants are continue under revision, and the Government Regulation No. 21/2005 (PP 21/2005) was the latest decree on this issue. PP 21/2005 was a modification of the joint-decree previously issued by the four Cabinet Ministers to accommodate the implementation of Cartagena Protocol, which was ratified by the Indonesian government in 2004.

PP21/2005 was issued to attain environmental safety, safety of food and/or feedstock produced by genetic engineering and their respective uses in farming, fisheries, forestry, industries, environment and public health. The approach used in assessing the risk is based on the principle of cautiousness, founded on solid scientific methods and also includes religious, ethical, socio-cultural, and aesthetical value considerations. In order to implement this government regulation, a system guideline is required to determine which institutions need to be involved, which procedures/protocols need to be followed and a clear legal structure. All of these require sufficient funding, whether it is for acquisition, operation, or monitoring. The funding would be required for research in laboratories, greenhouses, and field work for the purpose of gathering data requested by the Biosafety Committee (BC) through its Technical Team (Biosafety Technical Team or BTT) and their operational budgets, and other indirect costs required for fulfilling the aforementioned guidelines.

In some countries that have approved transgenic plants for commercial release, the total cost of releasing the transgenic plant commercially has been compiled and analysed.[4] One such example is the release of a mustard plant variety (a close relative of canola) in India, which has been transformed with a gene that has been used to transform canola in Canada and the USA. Since such a plant has never been released anywhere in the world, its producer (Bayer Inc) had to spend 3-4 million US $ for food safety tests, which were carried out in the USA and Europe. Another 1-1.5 million US $ had to be paid for research on the environmental risk analysis performed in India. Bayer had started this process in the early 1990s, but determined to stop its attempt to release transgenic mustard in India on 2003. This illustrates how costly it is to conform to and follow the regulations for a commercial release, even when the proponent decided not to continue trying to commercialise hybrid mustard in India at the end. Such high expenses clearly bear some consequences:

1. Farmers cannot utilise seeds of transgenic plants on their farmlands since their approvals are cancelled or withdrawn.
2. The high cost associated with the approval process would be passed on to farmers, causing seed price to increase beyond their reach.

Another aspect that needs to be considered is whether such expensive approval cost is within the reach of the public research institutions and universities or whether it is cost economic for one of their researchers to release transgenic products commercially. Could this mean attempts in constructing transgenic plants that often took years to complete and significant investments would reach a stalemate when the researchers seek regulatory approval? Many researchers in public institutions as a consequence would not consider conducting research on creating transgenic plants. So that society will lose the benefit of transgenic-technology to improve the common welfare.

This study attempts to calculate and analyse the expense for several research projects in four Indonesian government-funded institutions for the construction of transgenic plants and other experiments that need to be carried out to comply with regulatory requirements for commercial release of those plants. For comparison, similar expenses in the commercial release of a multinational company are also calculated and analysed.

Methodology

This study chose the sample institutions based on the following criteria: (i) institutions that carried out constructions of transgenic plants where the resulting plant is already at the stage of application for release within the next 2-3 years with the regulatory body; (ii) institutions that have obtained release approval; and (iii) institutions with a mandate to assess food and biological safety for commercial releases. The selected institutions are listed in Table 1.

Data were collected by using a structured questionnaire in interviewing subjects. The questionnaire was a modification of a standard questionnaire created by Dr Jose Falck-Zepeda for a similar study in several developing countries. In general, the data sought in the questionnaire for those institutions performing transgenic plant construction was as follows: (i) description of the institutions; (ii) type of transgenic plant research; (iii) direct and indirect costs for constructing the transgenic plants; (iv) description of the stages of transgenic research; and (v) facilities and equipments used for the construction of the transgenic plants. The data scope of the questionnaire for institutions already obtaining approval for release was as follows: (i) description of the institutions; (ii) type and research stages of the transgenic plants subjected to approval; and (iii) direct costs of research/assessment on the transgenic plants that would be released or had already been released. The data scope of the questionnaire for BFSTT (Biosafety and Food Safety Technical Team) included the operational costs of BFSTT and the number and status of applications evaluated.

Table 1: Sample (Institution) Selected for the Study

No.	Institution	Activity	Year of activity initiation and entering regulation phase
1	Biotechnology Research Center, Indonesian Institute for Science, Cibinong	Genetic engineering of rice plant for rice stemborer resistance using cry 1A gene	1996 (starting with rice tissue culture system coincided with plant transformation and etc).
2	Department Agronomy, Bogor Agriculture University, Bogor	Genetic engineering of potato plant resistance to fungi/nematode using chitanase gene	1994 (starting with gene isolation, then plant transformation and etc.. the project was temporarily suspended for a year)
3	Department of Plant Pests and Diseases, Udayana Univeristy, Denpasar	Genetic engineering of citrus plant for virus (CVPD) resistance.	1997/98 (starting with gene isolation, then plant transformation etc.)
4.	PTPN XI, Surabaya	Genetic engineering of sugarcane plant for drought tolerance using betA gene	1999 (starting with sugarcane tissue culture system, then plant transformation, etc.)
5	PT Monsanto (PT Monagro)	Application for commercial release of Bt-cotton and Roundup ready Corn	Application for commercial release of Bt-cotton (Bollgard) was in 1998 and RR corn in 2002
6.	Others (Biosafety and Food Safety Technical Team' coordinator, members, supporting staff, and related persons in related institutions)	Regulations, law, decree regarding biosafety and food safety of transgenic crops, and activity of the technical team including conducting meeting for data evaluation, number of persons attending a meeting, funding source to run the office, etc.	

Estimation of the cost of research in constructing transgenic plants was split into direct costs and indirect costs. Direct costs are expenses directly spent on research projects. This would include the costs of materials, wages, travel budget, and stationeries. Indirect costs are expenses not directly related to the research project, such as salaries (20 per cent of total wages), electricity, water, gas, equipment maintenance, and depreciation values of research equipments. Since payments for electricity, water, and gas bills is normally made for the whole institution, the actual cost for this is estimated according to the kind of equipment used in the project and the size of the lab carrying out transgenic projects. Data on indirect costs is also normally only available for the most recent year, while the construction of transgenic plants will already started several years before. Thus, the indirect costs for the previous years were calculated using a discount factor from the available data.

If the project is not handled exclusively by the sampled institutions, then the cost data would be obtained by cross-checking with the other institution participating in the said project.

The following table lists the assumptions used in calculating the cost of research and evaluation of transgenic plants:

Assumption we used in calculating the calculating cost of research and development and biosafety regulatory is as follows:

Variables	**Assumed Values**
Interest rate	18%
New inventory laboratory equipments	Estimated of equipment' value
Maintenance of equipment	1% of equipment' value
Depreciation	5% of equipment' value
Salary	20% of salary

To make the data more comparable with data from other countries, the resulting calculations were converted from the Indonesian currency (IDR) to dollar. In order to obtain the cost of research and evaluation for the current year, we calculate the present value using the following formula:

$$PV = A^*(1 + r)^n$$

Where :

A : Cost in year (current – n)

r : interest rate

n : number of years.

As previously mentioned, information on indirect costs normally is available only for the most recent year; therefore the cost for the previous years was calculated using a discount factor (DF) following the formula below:

$$DF = A^*(1 + r)^{-n}$$

Where :

A : Cost at a certain year

r : interest rate

n : number of years.

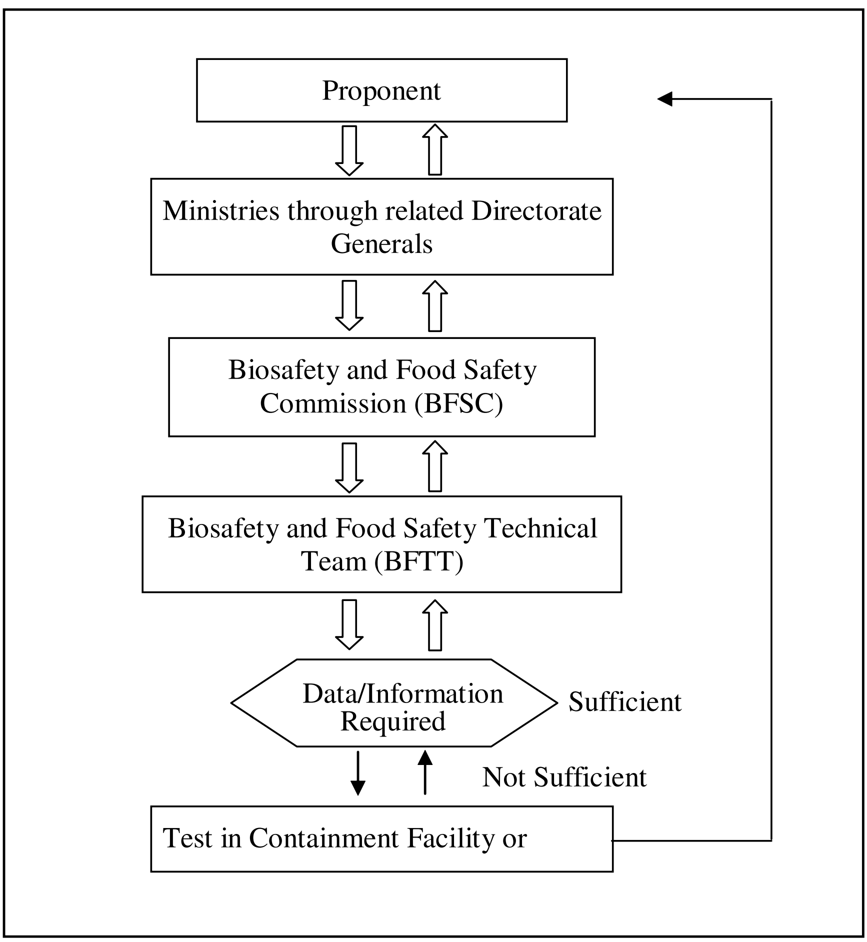
The information we collected from institutions that gained approval for commercial release (Monsanto Inc.) only covered the direct costs, since most research works were subcontracted to the various institutions. Information we obtain from Monsanto are only restricted to the research and other activities that were carried out in Indonesia during their field trials in compliance with the regulation for gaining approval in this country. Meanwhile, we had not successfully obtained the information on costs spent to do research and other activities performed outside of Indonesia (mostly in the USA).

Results and Discussion

I. Indonesian regulatory system for the biosafety of genetically engineered products

During the course of this study, Indonesia still used the guidelines set by the joint decree of Ministers known as SKB4M (SK Menteri No. 998.1/Kpts/OT.210/9/99; 790.a/Kpts-IX/1999;1145A/MENKES/SKB/IX/ and 1999 015A/NmenegPHOR/09/1999) for assessing the biosafety of genetically-engineered products. The decree set the procedure for analysing the biosafety and food safety of GM products to be released commercially in Indonesia. In addition, the appendix of the decree specified the membership of the Indonesian Biosafety and Food Safety Commission (BFSC). Article 39 stated that BFSC would be assisted by the Biosafety and Food Safety Technical Team (BFSTT), whose membership would be determined afterwards. The membership was later enacted by another joint Ministerial decree, SK No. LB.010.59.1.2000, 77/Kpts/9/2000 and KS.01.01.03380. The head, secretary, and members of the BFSTT are the Executives from the associated Ministries, Director Generals, Head of Directorates, Head of Research Centers, Head of PAU IPB, President of Biotechnological Association and Consortium, Head of Kehati Foundation (an NGO Representative), Head of Indonesian Consumer's Foundation, and Head of Indonesian Farmers Association, which added up to 21 members. The head and secretary of the BFSTT are *ex-officio*, and its membership consists of senior researchers from research institutions and universities from various disciplines. The membership is divided into five groups, namely: The Plant Group (11 members), Animal Group (7 members), Fishery Group (5 members), Microbial Group (11 members), and Food Group (17 members). The assessment procedures are summarised in Figure 1.

Figure 1: Scheme/Procedure for Risk Assessment based on *SKB4M*



Until this paper was written, the BFSC had only met several times to decide the status of the commercial release of the released Bt cotton from Monsanto. Most day-to-day activities were carried out by the BFSTT. The operational costs of the BFSTT were obtained from the proponent/applicants. Table 2 lists the BFSTT operational costs from 1998 to 2004.

Table 2: Operational Cost of BFSTT Activities

Year	Total Cost (million IDR)	Present Value of Cost (PV 2005, million IDR)	Present Value of Cost (PV 2005, thousand US$)
1998	50	159	16.1
1999	11.5	31	3.9
2000	10	23	2.9
2001	38	74	7.2
2002	104	171	18.4
2003	32	45	5.2
2004	12.5	15	1.6

The operational cost mostly covers the expenses for conducting meetings to assess the collected data, making decisions on the safety of certain genetically-engineered products, and creating guidelines for the food safety. The costs may differ each year, since they depend on the number of applications submitted to the team. As BFSTT also consists of different groups, the attendance level in meetings can also vary, depending on the case being examined. Table 3 lists the attendance level of members and their supporting staff.

Table 3: The Frequencies of BFSTT Meeting based on the Number of Attending Members*

No of members attending	No of meeting
5 - 10	5 meetings
11 - 15	9 meetings
16 - 20	9 meetings
21 - 25	4 meetings
25 - 30	1 meeting

*(n = 28 meets)

On an average, BFSTT meetings are held eight times per year. Most of the time, the meeting is attended by one coordinator and one leader, ten researchers, and three supporting staff. The cost of each meeting and the annual budget can be seen in Table 4.

Table 4: The Average Cost of BFSTT Meeting to Evaluate Dossier and/or Additional Required Data

Items	Direct cost per meeting		Indirect cost (10% of one month salary) per meeting		Total cost per meeting		Total cost of meeting per year (8x meets)	
	IDR	US$	IDR	US$	IDR	US$	IDR	US$
2 managerial honorarium	1,000,000	102.94	600,000	61.77				
11 researcher honorarium	3,300,000	339.72	2,750,000	283.10				
3 supporting staffs honorarium	600,000	61.77	450,000	46.32				
Meeting expenses	1,200,000	123.53						
Total	6,100,000	627.96	3,800,000	391.19	9,900,000,-	1,019.15	79,200,000,-	8,153.18

Although the BFSTT was established on 2000, research and assessments on the biosafety have been conducted since 1998. Four applications from Monsanto were submitted that year. By then, the activity was limited to biosafety assessment in a containment facility located in ICABIOGRAD. A small percentage of the budget was used to hold meetings to assess the biosafety issues and recommendations to be made. In total, there were five applications submitted in 1998, one application in 1999, one application in 2000, five applications in 2002, and two applications in 2003. Among these, only one application, Bt Cotton (Bollgard from Monsanto), gained approval for limited field releases in seven districts of the province of South Sulawesi. Seven applicants have been approved and recommended by the BFSTT as "safe for environment", but are yet to receive formal approval from the responsible Directorate Generals/Ministers for their commercial releases. The costs spent by each applicant for the BFSTT approval ranged from IDR 9 million (PV IDR 28 million) to IDR 51 million (PV IDR 83 million). This is more clearly illustrated in Table 5.

II. Recent Status of Research and Developments on the Construction of Transgenic Plants Activities in Indonesia

The purpose of this study is also to upgrade information on transgenic research in Indonesia so that the results published by the previous studies done on this topic may be updated.[5] The results are shown in Table 6.

Between 1996 and 2005, there were 31 transgenic plant construction activities, which were carried out on 20 different commodities (food crops, estate crops, horticultures, and forestry) involving 23 different introduced traits. The institutions working on those projects were Agency for Agricultural Research and Development (Ministry of Agriculture), Center for Biotechnology Research, Indonesian Institute of Science (State Ministry of Research and Technology), universities, several government-owned corporations (PTPN), and private corporations. Out of those 31 activities, only 16 were still active, while others were either temporarily suspended or terminated due to several reasons like funding termination, lack of progress, and alteration of priorities. Only two out these 16 activities ever made it to the regulatory process for approval.

Table 5: Budget for Environmental Risk Assessment Activities (million IDR)

Proponent	Commodity	Biosafety status	Experiment containment facility (FUT) at ICABIOGRAD	Dossier biosafety	Dossier food safety	Evaluation for FUT/ LUT data	Registration	Total	PV 2005 (x 1 million IDR)	PV 2005 (x 1,000 US$)
Monsanto	Corn-RR1 and corn RR-2	Safe for environment	5.5 (1998)			3.5 (1998)		9 (1998)	28.67	2.90
Monsanto	Bt-cotton	Safe for environment	8.0 (1998)			3.5 (1998)		11.5 (1998)	36.63	3.71
Monsanto	RR-cotton	Safe for environment	5.5 (1998)			3.5 (1998)		9 (1998)	28.67	2.90
Monsanto	RR-soybean	Safe for environment	5.5 (1998)			3.5 (1998)		9 (1998)	28.67	2.90
Monsanto	Bt-corn Mon-810	Safe for environment	8.0 (1998)			3.5 (1998)		11.5 (1998)	36.63	3.71
Pioneer	Bt-corn *cry*1Ab	pending	8.0 (1999)			3.5 (1999)		11.5 (1999)	31.04	3.98
Rosindo	Ronozyme	Safe for environment		10 (2000)				10 (2002)	22.88	2.47
Monsanto	Bt/RR cotton	Only for experiments	11.5 (2001)			6.5 (2001)		18 (2001)	34.90	3.40
Novartis	Bt-corn and Pacha-corn	Withdrawn by proponent		20 (2001)				20 (2001)	38.78	3.78
Monsanto	RR-corn NK603	Waiting for biosafety and food safety status	9.2 (2002)	10 (2002)	10 (2002)	21.8 (2002)		51.0 (2002)	83.79	9.05

Table 5 continued

Table 5 continued

Proponent	Commodity	Biosafety status	Experiment containment facility (FUT) at ICABIOGRAD	Dossier biosafety	Dossier food safety	Evaluation for FUT/ LUT data	Registration	Total	PV 2005 (x 1 million IDR)	PV 2005 (x 1,000 US$)
Monsanto	RR-corn GA21	Safe for environment			10(2002)			10 (2002)	16.43	1.77
Monsanto	RR-soybean	Safe for environment			10 (2002)			10 (2002)	16.43	1.77
Dupont	Bt-corn *cry*1Ab	Waiting for the status		10 (2002)				10 (2002)	16.43	1.77
IIS (LIPI)	Bt-rice for permit to run confined field trials					6 (2002)		6 (2002)	9.86	1.06
PTPN XI	Sugarcane bet-A for permit to run confined field trial		8 (2003)			4 (2003)		12 (2003)	16.71	1.95
PT Behn Meyer	Finase P and L	Safe for environment		20 (2003)				20 (2003	27.85	3.25
Dupont	Bt-corn *cry*1F	Only for registration					12.5 (2004)	12.5 (2004)	14.75	1.64

(….) : Number in parenthesis indicates year of activity.
FUT = containment facility at the ICABIOGRAD; LUT = confined field trial legally permitted by the BFSTT.

Table 6: The Status of GM Crop Researches in Indonesia (2005)

Crop	Lead Institution	Target trait	Gene	Status
Rice	ICABIOGRAD	Resistance to rice stem borer	*cry*	Plasmid reconstruction, plant transformation (on-going)
	RCB- IIS	Resistance to stem borer	*cry*	Limited field trials for plant phenotype (morphological performance, level of plant resistance to major rice pests and diseases) and impact on non-target spesies(on-going)
	RCB- IIS	Resistance to blast	antc, psmp	Bioassay in greenhouse (containment facility)(on-going)
	RCB- IIS	Resistance to blast	chitinase	Greenhouse (suspended)
	RCB-IIS	Drought tolerance	Homeobox	Bioassay in green-house (containment facility) (on-going)
	RCB-IIS	Brown planthopper resistance	Snowdrop Lectin	Green-house (suspended)
Maize	ICABIOGRAD	Stem borer resistance	*cry*	Green-house (suspended)
	ICABIOGRAD	Stem borer resistance	Pin II	Green-house (suspended)
Sweetpotato	ICABIOGRAD	Insect resistance (sweet potato weevil)	Pin II	Green-house (suspended)
	ICABIOGRAD	Viral resistance	Coat protein	Green-house (suspended)
Soybean	ICABIOGRAD	Podborer resistance	Pin II	Green-house (suspended)
	ICABIOGRAD	Podborer resistance	*cry*	Green-house (suspended)
Papaya	ICABIOGRAD	Delay ripening	Antisense ACC oxidase	Screen house, phenotype study(on-going)
Cacao	BRUEC-semi private	Podborer resistance	*cry*	*In-vitro* planlet (suspended)
Coffee	BRUEC	Fungi (rust) tolerance	chitinase	*In-vitro* planlet (suspended)
Sugarcane	PTPXI-ISRI	Drought tolerance	Choline dehydro genase (bet A)	Limited filed trials for morphological characteristic, and sugar content (on-going)
	BAU-public	Phosphor absorption efficiency	Phytase	*In-vitro* planlet (on-going)

Table 6 continued

Table 6 continued

Crop	Lead Institution	Target trait	Gene	Status
Chili pepper	BAU	Resistance potato virus Y	Coat protein	Green-house (Terminated)
Groundnut	ICABIOGRAD	Virus PStV resistance	Coat protein	Green-house facility (suspended)
	BAU	Virus PStV resistance	Coat protein	Green-house facility (suspended)
Potato	BAU	Fungal/nematode resistance	chitinase	Green-house facility(on-going)
	BAU	Potato virus P and Y	Coat protein	Greenhouse(terminated)
	ICABIOGRAD-IVRI-public	Late blight(*Phytoptora infestan*)	RB gene	Plant transformation (on-going)
Tomato	ICABIOGRAD-IVRI	Tomato yellow curl virus	Coat protein	Green-house(on-going)
	ICABIOGRAD-IVRI	Cucumber mosaic virus	Coat protein	Green-house(on-going)
Teak	Bandung Institute for Technology - public	Prolong vegetative stage	Leafy gene	*In-vitro* plantlet (suspended)
Orchid	Gajah Mada University-public	Improved quality	Knox gene	*In-vitro* plantlet(on-going)
Citrus	Udayana University-public	CPVD resistance	Newly explored	Green-house facility (suspended)
Eucalyptus	PT Ararabadi-Indah Kiat- Pulp/forestry private company	Disease resistance	Un-known (confidential)	Green-house(on-going)
Cabbage	Airlangga University-Gajah Mada University-public	Disease resistance	Glucanase	*In-vitro* plantlet (terminated)
Cassava	RCB- IIS	Free amylose	Blenching enzyme (be-1 and be-2)	Green-house(on-going)
Acasia	RCB- IIS	Lignin content	4CL	Gene isolation, plasmid construction, In-vitro plantlet(on-going)
Sengon (*Paraserianthes falcataria***)**	RCB- IIS	High growth	Xylolase and Xylo-glucanase	Green-house(on-going)

III. R&D Transgenic Plant Construction Activities in Indonesia

III.1. Construction of Transgenic Potatoes Resistant to Fungi/ Nematodes at the Department of Agronomy, Bogor Agricultural University (BAU)

The research on transgenic potatoes resistant to fungi/nematodes was a collaboration between researchers from the Department of Agronomy (Faculty of Agriculture, Bogor Agricultural University), Department of Biology (Faculty of Mathematics and Science, Bogor Agricultural University), and Plant Research International (PRI) in Wageningen, The Netherlands.

The project began in 1994 with isolation of the chitinase gene from *Aeromonas caviea* strain W57b, which was obtained from a soil sample from the Island of Bangka. The gene isolation was performed by Dr. Suwanto et al at the Department of Biology, Bogor Agricultural University, in a three year project funded by RUT. The next phase was the construction of plasmids, vectors, and potato transformations, which was completed in 1998-1999 by Dr. Armini Wiendi for her PhD study in a sandwich programme between Bogor Agricultural University and PRI. The resulting material was transported to Indonesia for further research. The transformants were subsequently regenerated and acclimatised for growth in a greenhouse. More studies were performed at BAU to confirm the gene integration, and the transgene function was also confirmed using enzymatic assays. Greenhouse testing was carried out at Pasir Sarongge between 2002 and 2004 to assess the phenotype and resistance to pests and diseases. Overall, this project was funded by RUT grants for six years (two periods of 3 year grant) and PRI (in the form of scientific training at PRI) for nine months. The details of the project expenditure are listed in Table 7.

It can be seen that during the eight years that the project was carried out, a total of IDR 1.5 billion (PV 2004 IDR 2.5 billion), which was equivalent to US $ 317,000 (PV 2004 US $ 650,000), has been allocated for it. However, this project was subsequently stopped or downsized due to a lack of funding.

The resulting product has not been registered for approval in accordance with the joint ministerial decree, but some preliminary studies have been carried out to obtain some data that would be required for release approval. One example was the greenhouse testing on an

Table 7: Actual and Present Value of Cost of R&D of Potato Resistance to Fungi/Nematode at BAU

Year	Activity	Actual Total Cost	PV Total Cost	Actual Total Cost	PV Total Cost
		(000 IDR)		(000 US $)	
1994	Gene Isolation	139,586	415,472	64.504	191.99
1995	Gene Isolation	146,712	365,259	65.119	162.12
1996	Gene Isolation	155,120	325,076	66.093	138.51
1997/1998	Plasmid/vector Construction *	133,835	236,624	26.039	36.89
1999/2000	Plasmid/vector Construction, plant transformation, and analysis insert gene *	148,944	294,969	18.661	29.87
2001	*In vitro* enzymatic analysis	111,922	139,855	11.884	17.12
2002	Plant phenotype (green house)	185,866	216,865	19.998	25.41
2003	Plant phenotype, plant resistance to *Fusarium* and *Alternaria* (green house)	215,102	231,122	22.774	22.51
2004	Plant phenotype, plant resistance to *Fusarium* and *Alternaria* (green house)	244,800	244,800	22.504	26.43
	Total	**1,481,887**	**2,470,043**	**317.58**	**650.86**

Notes: - Present Value (PV) for 2004, with interest rate of 18%
- Not include food safety assessment/analysis
- *Experiments were conducted at PRI, Wageningen, the Netherland (the materials and equips were subsidised)

experimental plot owned by Bogor Agricultural University at Pasir Sarongge to study the phenotype of the plants. According to the researcher in charge, this is necessary since potatoes are normally planted at high altitudes, while containment facilities for transgenic plants that are available in Bogor and Cibinong were both located at low altitudes, which made them unsuitable for growing potatoes. Also, the team responsible for the evaluation of experiment at the containment facility was still dominated by food crop specialists.

III.2 Construction of Transgenic Citrus Resistant to CPVD at the Department of Plant Pathology, Faculty of Agriculture, Udayana University (Denpasar)

The development of Citrus resistant to CPVD began in 1997 with the isolation of a resistance gene toward CPVD from *Triphacia aurantolia* (jeruk kit kit), a resistant wild citrus species. The gene was later introduced into some local citrus varieties called jeruk keprok by Kintamani and Soe, using *in planta* agrobacterium transformation method.[6] This project was funded by RUT for six years (two periods of three year grant) and JSPS for two years. Part of the research on gene isolation, sequencing, and plasmid construction was performed in Japan (University of Nagoya, Japan). The part of the project carried out in Japan was largely subsidised by the University of Nagoya, and utilised equipments available at the university laboratories. The total funds consumed by the project are summarised in Table 8.

It can be seen that this eight year project in total has used IDR 3.1 billion (PV 2004 IDR 5.6 billion) of research funds, or equal to US $ 370,000 (PV 2004 US $ 641,000). Recently, this project was downsized due to a lack of funding and the only remaining activity was the maintenance of two transgenic plants in a greenhouse facility at Udayana University. Moreover, the principal investigator does not have any intention of releasing these plants commercially due to difficulties in fulfilling the complex regulatory process and its associated high costs. The result of this project is currently directed toward the development of biopesticides for CPVD, even though the project has generated two patents in Indonesia for two open reading frames (patent number P-00200400345 and P-00200400346).

III.3 Construction of Transgenic Drought-Resistant Sugarcane at PTPN XI, Surabaya

The construction of drought-tolerant sugarcane was started in 1999. The gene, *bet A,* was donated by PT Ajinomoto. It encodes an enzyme

Table 8: Actual and Present Value of Cost of R&D of Citrus Resistance to CVPD at Udayana University

Year	Activity	Actual Total Cost	PV Total Cost	Actual Total Cost	PV Total Cost
		(000 IDR)		(000 US $)	
1997/1998	Gene Isolation, plasmid/vector construction*	143,133	455,947	48.49	122.52
1998/1999	Gene Isolation, plasmid/vector construction*	150,897	407,355	15.28	32.49
1999/2000	Gene Isolation, plasmid/vector construction*	160,059	366,176	20.50	36.99
2000	Plant transformation**	924,269	1,791,953	108.30	202.18
2001	Plant transformation**	1,110,226	1,824,137	108.15	172.45
2002	Confirmation of gene, integration, and gene expression, gene function , phenotype of plant	177,481	247,124	19.16	22.50
2003	Confirmation of gene, integration, and gene expression, gene function , phenotype of plant	208,441	245,960	24.32	26.25
2004	Confirmation of gene, integration, and gene expression, gene function , phenotype of plant	233,900	233,900	26.03	26.03
	Total Cost	**3,108,406**	**5,572,552**	**370.23**	**641.42**

Note: (i) Some part research was done (subsidised) in Nagoya University (Japan).
(ii) Research was funded by JSPS (Japan grant).
- Present Value (PV) for 2004, with interest rate of 18 per cent.
- Does not include food safety assessment/analysis.

called *choline dehydrogenase*, which oxidizes *choline* to *glycine betaine*.[7] *Glycine betaine* is an osmo-protectant. The target plants were local sugarcane varieties. Currently, the transformants are maintained through vegetative propagations (stem cuttings) and release approval has already been applied for these. In compliance with the regulation, it underwent evaluations at the containment facility at ICABIOGRAD Bogor in 2003, and confined field tests were also carried out in East Java (Asembagus and Jatiroto). The total budget that has been spent in four years reached IDR 1.3 billion (PV 2004 IDR 2.3 billion), or equal to US $ 154,000 (PV 2004 US $ 255,000). The details can be seen in Table 9.

III.4. Construction of Transgenic Rice Resistant to Stem Borers at the Indonesian Institute of Science

The project was initiated in 1996, funded by grants from the Rockefeller Foundation and the Indonesian Government through APBN. The Rockefeller Foundation sponsored the research from 1996 to 2000. The transgene, *cry* 1A(b), was a gift from Altosar. Research activities began in 1996 with the establishment of tissue culture system, followed by the transformation of rice plants as summarised in Table 10.

IV. The Total Cost to Comply With the Biosafety Requirements for Commercial Releases

IV.1 Government Research Institutions

IV.1.1 Drought-Resistant Transgenic Sugarcane (PTPN XI)

In 2003, PTPN XI registered the transgenic sugarcane to BFSC through BFSTT, to evaluate its phenotype and invasiveness at the containment facility in ICABIOGRAD. Evaluation of the stability of the transgene was simultaneously carried out in greenhouses and laboratories at PTPN XI. Authorisation for the confined field trials were granted by BFSTT in 2003, and was implemented in two locations in East Java (Jatiroto and Asembagus). By 2005, the total expense paid by PTPN XI to fulfill these regulatory requirements was IDR 178 million (Table 11).

IV.1.2. Transgenic Rice Resistant to Stem Borers (Indonesian Institute of Science)

After seven years of development, the resulting transgenic plants were subjected to a confined field trial in 2003. That year, the Bt-rice was

Tabel 9: Actual and Present Value of Cost of R&D of Sugarcane Drought Tolerant at PTPN XI

Yeat	Activity	Actual Total Cost	PV Total Cost	Actual Total Cost	PV Total Cost
		(000 IDR)		(000 US $)	
1999 (Jul-Dec)	Tissue culture system for sugarcane	130.481	370.883	16,71	47,49
2000 (Jan- Jun)*	Plant transformation	773.774	1.079.694	90,67	126,52
2000/2001(Jul-Jun)	Confirmation of gene integration	237.036	468.833	23,09	45,67
2001	Lines selection	143.651	246.917	13,99	24,05
2002	Confirmation of gene expression by in vitro enzymatic analysis	95.417	105.706	10,30	11,41
	Total	**1.380.359**	**2.272.024**	**154,76**	**255,14**

* In 2000 PT. Ajinomoto sponsored the research avtivity by donating equipments and chemicals valued as around 600 million IDR.

Table 10: Actual and Present Value of Cost of R&D and Regulatory of Bt-Rice, RCB-IIS

Yeat	Activity	Actual Total Cost	PV Total Cost	Actual Total Cost	PV Total Cost
		(000 IDR)		(000 US $)	
1996	Tissue culture system for rice	352.716	1.257.105	150,284	535,62
1997	Plant transformation and regeneration	393.552	1.185.332	133,317	401,54
1998	Plant transformation and regeneration	633.879	1.763.526	64,190	178,58
1999	Confirmatin of gene integration, expression, and stability of gene integration	492.190	1.143.948	63,028	146,49
2000	Confirmatin of gene integration, expression, and stability of gene integration	633.941	1.285.474	68,571	150,63
2001	Crossing between transgenic Vs popular variety, Gene Stability	202.753	259.079	19,750	25,24
2002	Crossing between transgenic Vs popular variety, Gene Stability	215.980	254.562	23,321	27,49
	Total	**2.925.009**	**7.149.026**	**522,462**	**1,466**

(i) Does not include food safety assessment/analysis.

Note:
- Present Value (PV) for 2005, with interest rate of 18 per cent
- The research was funded by the Rockefeller in the first 5 years apart from Indonesian government funding.

The total budget spent during the seven year bt-rice construction project (1996-2002) was IDR 2.9 billion (PV IDR 7.1 billion), or equal to US $ 522,000 (PV US $ 1.5 million).

Tabel 11: Direct Cost of Drought Tolerance Transgenic Sugarcane Biosafety Regulatory Phase

Activity	**Total actual cost (million IDR)**	**Total PV (million IDR)**	**Total actual cost (US $)**	**Total cost PV (US $)**
Dossier filling for l risk assessment (2003)	4	7,8	470	905
Containment facility Test at ICABIOGRAD (2003)	8	13,1	933	1.534
Gene stability and plant phenotype at PTPN XI' green-house (2003)	50	69,6	5.834	8.123
Confined field trials (plant phenotype, drought tolerance, sugar content etc) in East Java (2003/2004)	58	68,4	6.455	7.617
Confined field trials (plant phenotype, drought tolerance, sugar content etc) in East Java (2004/2005)	58	58,0	5.961	5.961
Sub-total biaya	178	216,9	19.649	24.139
Gene-flow	?			
Non-target spesies	?			
Food safety	?			
Feed safety	?			
Data evaluation	?			
Total	?			

Tabel 12: Direct Cost of Transgenic Rice Resistance to Stemborer Biosafety Regulatory Phase

Activity	Actual Total cost (million IDR)	Total cost PV (million IDR)	Actual Total cost (US $)	PV 2005 (US $)
Dossier untuk pengkajian keamanan hayati	6.0	9.8	650	1,060
Non target impact (serangga pengendali hayati)	60.0	83.5.	7,000	9,750
Non target impact (serangga pengendali hayati)	70.0	82.6	7,790	9,190
Non target impact (bakteri tanah)	900	90.0	9,250	9,250
Sub-total	266.0	266.0	24,250	29,250
Gene-flow*	50.0	42.4	5,140	4,350
Uji multi lokasi* (2 musim tanam, 10 unit @ 20 juta rupiah)	400.0	287.3	41,110	29,520
Evaluasi data-data (non-target impact)*	10.0	8.5	1,030	870
Evaluasi data-data (gene-flow)*	10.0	722	1,030	740
Total	696.0	611.3	73,000	64,730

Note: *estimation cost (the activity not yet done).

also registered to get approval for commercial release. The approval process began with an authorization from the BFSC through the BFSTT for conducting confined field trial studies in West Java (held in Sukamandi, Karawang, Pusakanegara, and Indramayu). The field study was carried out in three years to evaluate the effect of Bt toxin carried by the transgenic plants on non-target species, especially insect predators and soil microbes. On 2006, there will be more studies on gene flow from the transgenic rice (Table 12). All the costs listed in Table 12 below were direct costs.

Table 12 shows that up to 2004, IIS had spent IDR 226 million (PV IDR 266 million), which equals US $ 24,200 (PV US $ 29,000). According to Dr. Inez S. Loedin, IIS would need an additional IDR 470 million to complete all the requirements of the approval processes listed in Table 12. That additional fund would be required for gene flow studies, multi-location testing, and for facilitating meetings of BFSTT and the Team for Varietal Release to evaluate the collected data from the aforementioned studies.

IV.2 Multinational Companies

IV.2.1 Bt-Cotton Resistant to Bollworm (Monsanto)

Indonesia was the first country in South East Asia that approved commercial field releases of transgenic plants. To obtain a permit to release their Bt-cotton, Monsanto had to comply with the regulatory processes by conducting evaluations and research on Bt-cotton at the containment facility owned by the ICABIOGRAD. The approval for a limited field release at seven districts in South Sulawesi was obtained in 2001. The total to complete the process was approximately IDR 919 million (PV IDR 974 million) of direct cost or approximately US $ 93,000 (PV US $ 99,800), as summarised in Table 13. The time spent on additional research and assessments was merely 2-3 years. It only took less than a year to attain a safe for environment status from the BFSTT, but it took longer to actually get the permit from the BFSC and the Minister of Agriculture. A limited permit was finally issued with the following conditions:

(i) The permit was only valid for one year
(ii) Bt cotton could only be planted at seven districts in the province of South Sulawesi.
(iii) The release must be monitored by an appointed team.
(iv) Harvested seeds and other byproducts must not be used for feed nor food.

Table 13: Direct Cost of Transgenic Cotton Resistance to Cotton Boll worm

Year	Activity	Actual Total Cost	PV Total Cost	Actual Total Cost	PV Total Cost
		(million IDR)		(US $)	
1998	Dossier for risk assessment	10.0	16.4	1,010	1,660
	Morphological characteristic (containment facility at ICABIOGRAD)	16.0	26.3	1,620	2,660
1999	Confined Field Trials	30.0	41.8	3,840	5,350
2000	Multi-location trials	140.0	165.2	16,400	19,360
	Technical Team meeting fee	10.0	11.8	1,170	1,380
2001	EIA(environment Impact Assessment)-Gene Flow	125.0	125.0	12,180	12,180
	EIA-Non target impact	193.0	193.0	18,800	18,800
	EIA-soil microbes	395.0	395.0	38,480	38,480
Total	919.0	974.5	93,500	99,870	

Note: Present Value (PV) for 2005, with interest rate of 18 per cent.

Table 14: Actual and Present Value of Regulatory Cost of Corn- RR NK603 (Monsanto)

Year	Activity	Actual Total Cost	PV Total Cost	Actual Total Cost	PV Total Cost
		(million IDR)		(US $)	
2002	Dossier for risk assessment	10.0	16.4	1,080	1,770
2002	Morphological characteristic				
	1. Non target impact, invasiveness in contained facilities	16.0	26.3	1,730	2,840
	2. Limited trial at 3 locations	30.0	49.3	3,240	5,320
2002	Dossier for food safety	10.0	16.4	1,080	1,770
2002	technical meeting (twice)	15.0	24.6	1,620	2,660
	Total Expended Cost	**81.0**	**133.1**	**8,750**	**14,370**
	Estimated future expenses :				
?	1. Multi-location trials (10 units, 2 seasons, app 9 million)	180.0	180.0	18,530	18,530
?	2. Variety released Team meeting to evaluate multi- location trials data	15.0	15.0	1,540	1,540
?	3. Confined Field Trials				
	a. EIA-Gene Flow	125.0	125.0	12,870	12,870
	b. EIA-Non target impact	193.0	193.0	19,870	19,870
	c. EIA-soil microbes	395.0	395.0	40,660	40,660
?	4. Feed safety studies (fish, poultry)	15.0	15.0	1,540	1,540
?	5. Additional Technical meeting (3 times)	30.0	30.0	3,090	3,090
TOTAL	**1,034**	**1,086**	**106,850**	**112,480**	

Note **:** - Present Value (PV) for 2005, with interest rate of 18 per cent.
- ? not yet mentioned.

(v) The permit would be reevaluated if some unintended negative consequences that could harm the environment and human health were found.

In 2001, about 6,639 farmers planted Bt-cotton over a 4,363 hectare area with an average yield of 1.2 tons/hectare. By 2002, the plantation area increased to 5,124 hectares and 10,424 farmers were involved. The average yield also increased to 2.2 tons/hectare, which was 2-3 times higher than the average yield of non-transgenic cotton varieties.[8] However, for some reasons Monsanto decided not to continue the plantation of Bt-cotton in 2003.

IV.2.2 Roundup-Ready NK603 Corn

Monsanto started the application process for the herbicide-resistant corn in 2002. Originally, approval application was made for two roundup-ready corn varieties: RR GA21 and RR NK603. However, Monsanto subsequently decided to focus on RR NK603 for the Indonesian market. Table 14 shows that since 2002 the company has spent around IDR 81 million (PV IDR 133 million), which equals US $ 8,700 (PV US $ 14,000). Until this paper was written, a release permit had not been issued for RR NK603. It is expected that more research and evaluations would need to be carried out to get the approval, which means that around IDR 953 million or US $ 106,000 would be needed to pay for the whole regulatory processes.

Discussions

Based on the tables presented previously, it can be seen that the research cost for constructing and releasing transgenic plants is varied. This variation was caused by differences in the commodities used as the target plants, the trait-introduced, the type of research, the location of the research, the institutions performing the research (government-owned companies, universities, independent public institutions), and the source of funding. Variations can also happen on very similar research projects due to differences in approach, methods, and/or parameters to be studied. Table 15 lists the budget needed for both the construction and approval processes.

Table 15 shows in this case that the construction of transgenic plants required an actual budget of IDR 1.4-3.1 billion (PV IDR 2.4-7.1 billion), which equals to US $ 171,000-522,000 (PV US $ 641,000-1,500,000). These numbers clearly mean that constructing transgenic

Table 15: Estimated Cost for R&D and Biosafety Regulatory of Several Transgenic Crops in Indonesia*

Crop	Year of activity	Initiated step of activity	Present activity status (2004/2005)	Estimated cost			
				Actual (million IDR)	PV (million IDR	Actual (thousand US$)	PV (thousand U$$)
Potato resistance to fungi/ nematode	1994-04	Gene isolation	Green house (plant phenotype dan confirmation of gene integration and expression and function)	1.431	2.470	317,5	650,8
Citrus resistance to CVPD	1997-04	Gene isolation	Green-house (plant phenotype dan confirmation of gene integration, expression, function)	3.108	5.572	370	641
Sugarcane tolerant to drought	1999-02	Plant transfor-mation	Confirmation of gene integration and expression	1.380	2.272	154,76	255,14
	2002-05	Biosafety regulation	Confined field trials (plant phenotype, sugar content, drought tolerance)	178	216,9	19,6	24,1
Rice resistance to stemborer	1996-02	Plant transfor-mation	Confirmation of gene integration, expression, and transformation stability	2.925	7.149	522,5	1,466
	2002-05	Biosafety regulation	Confined field trials for non-target impact (natural enemies and soil microbes)	226	266	24,2	29,25
Bt-cotton	1998-02	Biosafety regulation	Contained facility test (plant morphology), confined field trials, multilocation tests, environment impact assessment (non-target impact-natural enemies, soil microbes)–gene-flow). The transgenic Bt-cotton crop had been released for commercial use in 2001, 2002, but the proponent did not extend the approval or continue bt-cotton business in Indonesia in 2003	919	974,5	93,5	99,9
RR-Corn	2002-02	Biosafety regulation	Containment Facility Test (plant morphology) at ICABIOGRAD, confined field trial in 3 locations, assessment for environment and food safety. Not yet gained the release approval	81	133	8,7	14,4

Note: * Direct cost only.

plants is neither a cheap nor trivial activity. The project can take more than four years just for the construction stage, and further time and resources would need to be allocated to comply with the regulatory procedures to obtain the permit so that farmers can plant these on their fields.

The cost of the regulatory process can be inferred from the case of Monsanto and the Indonesian Institute of Science when they attempted to gain approval for their transgenic plants. Bt-cotton, which is neither a food nor feed crop, had to undergo three years of evaluation with a steep cost of IDR 919 million (equal to US $ 99,000). It is potentially worse for food crops, as in the case of RR NK603 corn. After five years of evaluation for approval that cost IDR 81 million (PV IDR 133 million), it has not even met the requirements set by the BFSC through the BFSTT for its commercial release. It is estimated that IDR 900 million of additional fund would be required for completion of the regulatory procedures. It should be noted that this RR NK603 corn has already been released commercially in several countries, including The Philippines.[9]

The cost of the regulatory processes leading to commercial release of transgenic plants that must be paid by institutions (private and government-owned) in other countries will be described as a comparison. In India, the cost of government approval to release the Bt-cotton (which had already been released in the USA) was US $ 900,000 (excluding salaries). The process took 3-4 years and only consists of additional trials conducted in India. Assessments on transgenic plants that have never been released in other countries would cost more and need a longer period of evaluation. Nevertheless, the cost incurred to government-owned institutions would be lower. It is estimated that the cost of approval for transgenic Bt-eggplant constructed by a government institution would be around US $ 53,000. In the future, releasing transgenic plants in India, like Bt-corn, for example, would cost around US $ 500,000 to comply with the regulatory requirements.[10]

China, on the other hand, is likely to charge less than India. The expenses paid by private companies to gain approval in China were only US $ 65,000 to 89,000, while the government institutions in China would only need US $ 53,000 to 61,000. Only a small fraction of those approval cost were needed for the biosafety evaluation/assessment (around US $ 15,000), while the rest was mainly used for breeding purposes. Meanwhile, the cost of food safety assessment is relatively more expensive. For example, the cost of food safety assessment for transgenic mustard (a close relative of canola) was US $ 3-4 million in the USA and Europe. In China, a similar process carried out on Bt-cotton and Xa-21 rice would cost US $ 600,000 .[11]

It is difficult to make a cost comparison between private companies and the government institutions in Indonesia because there have not been any commercial releases of transgenic plants produced by government institutions. However, some comparisons could be done if we break the regulatory processes down into stages, such as dossier filling. Private companies like Monsanto were expected to pay around IDR 10 million for dossier filling, while government institutions like IIS and PTPN XI are only expected to pay IDR 6 million and IDR 4 million, respectively. For an environmental risk assessment study like the effect of Bt on non-target organisms, IIS only paid IDR 80 million whereas Monsanto had to shell out IDR 193 million. For gene flow studies, IIS also would pay around IDR 80 million compared to Monsanto that had to pay IDR 125 million (Table 16).

For Table 16, we were also attempting to obtain some information/ data from several laboratories performing part of the evaluation studies. From our discussion with one of the members of the BFSTT, it was concluded that a standardised test or a minimal requirement system for risk evaluation is definitely required, like the number of samples, replicates, observed parameters, the length of experiment, and the number of seasons over which the experiment should be conducted. Therefore, the result is more universally applicable in deciding the safety issues of the genetically-engineered products.[12]

Like the cost of research in transgenic construction, there is also a significant variation in the cost of the approval process. It depends on whether the applicant is a private company or a government-affiliated institution. This holds true for many countries. The approval cost is also contingent on the number of additional evaluations that need to be carried out in the country where the application is lodged (in-house assessments). There is no available standard for the type of information/data that needs to be supplied in this in-house assessment process, technical and cost-wise. As an example, the following table summarises the type of data that needs to be supplied for risk assessments in other countries.

Table 16: Estimation of the Cost of Some Tests for Risk Assessment (Environment and Food/Feed Safety in Indonesia (in IDR)

Test type	Food analysis lab at BAU	Post Harvest Lab	ICABIOGRAD Biology moleculer' lab	Animal husbandry nutrition lab, BAU	Fish nutrition lab, BAU	Research Institute for Rice- Indon Inst for Scienceb	Gajahmada University, Univ. Hasanudin, BAU, Monsanto
Proximate	390 thousand	140 thousand	80 thousand				
Poultry feeding				1.2 billion			
Goat feeding				1.2 billion			
Cat fish feeding					50 million		
Non-target spesies (serangga)						70-80 million	193 million
Non-target spesies (mikroba tanah)						90 million	190 million
Gene-flow						80 million	125 million

Tabel 17: Type of Data and Experiment Needed for Risk Assessment (Environment, Food, Feed Safety) for Transgenic Crops (Dr. Jose Falck-Zepeda, 2003*)

Data	
Product characterization	Unique identifier, reference material, validation, gene stability, protein purification, mechanism of action, homology, digestability, etc
Food/feed safety	Toxicology (acute and repeated oral, mutagenicity and developmental, sub-chronic and chronic), oncogenicity, effect on immune and endocrine system, dietary characteristic, norwegian rat allergenicity studies, monkey feeding, dog feeding, nutritional value, micotoxin analysis, anti-nutrient
Feeding studies	Poultry, fish, cow, buffalo feeding studies
Compositional analysis	Proximal studies, aminoacid sequence
Ekspression studied	Leaf, stem, floral, seed, oil etc
Environmental safety	Non-target impact (predator, parasites, bee, ants, soil microbes, herbivore, storage pests, weeds), gene-flow (develop model, field studies of pollen flow, development of insect resistance strategy (baseline resistance studies).

Note: *Summary from the questionare template that we used in this survey

There was also no consensus on the number of years and replications of the tests necessary for the risk assessment. The same applies for food safety evaluations. What types of information/data were needed to be supplied? Would the information/data collected from other countries be applicable as well? What conditions are necessary for in-house assessments?

Apart from data that originated from Indonesian researchers and laboratories, we also tried to review the cost of biosafety and food safety assessments in other countries like India and China (Table 18) in order to estimate the necessary costs required to gather the necessary data for the risk assessment process.

Prospects and Challenges for Research, Development, and Application of Transgenic Plants in Indonesia

A continuous expansion of the plantation area of transgenic plants worldwide indicates that there is a significant increase in public

Table 18: Estimation of Cost of Several Test for Risk Assessment in India and China

Type of experiment	Estimated cost (US$)	References
Goat feeding study-90 day	55,000	India (Pray *et al*., 2005)
Cow feeding study	10,000	India (Pray *et al*., 2005)
Water buffalo feeding study	10,000	India (Pray *et al*. 2005)
Pollen flow	40,000	India (Pray *et al*. 2005)
Poultry feeding study	5,000	India (Pray *et al*. 2005)
Fish feeding study	5,000	India (Pray *et al*. 2005)
Brown Norway rat allergenicity study	150,000	India (Pray *et al*. 2005)
Socio economic study	15,000	India (Pray *et al*. 2005)
Baseline resistance study	20,000	India (Pray *et al*. 2005)
Limited field trial	5,000	India (Pray *et al*. 2005)
Resistance study	20,000	India (Pray *et al*. 2005)
IPM package	10,000	India (Pray *et al*. 2005)
Food safety-anti nutrients	120	China (Pray *et al* 2006)
Food safety-rat feeeding (90 day)	14,500	China (Pray *et al* 2006)
Environment safety	32,800	China (Pray *et al* 2006)
Environment field trial	1,500-5,000	China (Pray *et al* 2006)

acceptance of transgenic crops. There is also an increase on the number and variety of transgenic plants being constructed and released for commercial applications. This was accompanied by growth in the amount of investments in this field as well. By 2005, a total of 90 million hectares of land in 21 countries was cultivated with transgenics grown by 8.5 million farmers.[13] The number of applications for field trial in several developing countries has also increased. For example, in 1997 China has received 1044 applications for confined field trials and 777 of those were approved, which consisted of 60 different transgenic plants. By 2003, approvals for commercial releases were granted for 30 varieties of Bt-cotton, and this number further increased to 140 in 2004.[14] In the Philippines, four varieties of transgenic corn (NK603, Bt11, Mon810, and NK603xMon810) have been approved for commercial release.[15]

As an agrarian country, Indonesia is keen to implement genetic engineering to further improve the agricultural output and the welfare of its citizen. This is reflected in the willingness of the government to adopt the application of transgenic plants, even though everything was carried out under the principle of cautiousness. In the current era of globalisation, it is difficult to isolate one country's policy from the others. This is even more pronounced under the regime of international conventions like CBD (Cartagena Protocols), GATT, WTO, and others.

Consequently, in order to increase its competitiveness in the global arena, Indonesia needs to put in place a solid research and regulatory system to encourage positive developments and applications of the transgenic plants.

Prospects and Challenges of Research for Constructing Transgenic Plants in Indonesia

Constructions of transgenic plants have been initiated since 1996 in Indonesia. At the same time, regulations on genetically engineered products were also issued. However, the progress of research and applications of transgenic plants in Indonesia has not been as rapid as expected.

Several developing countries have also constructed their own transgenic plants. There have been 209 transformation projects carried out in 76 institutions from 16 developing countries.[16] Like Indonesia, generally these countries initiated the projects at the beginning or middle of the 1990s. Indonesia is one of the most active developing countries in building up its plant genetic engineering programme, with 11 per cent of the total transformation events taking place in its laboratories (209 transformation events). As a comparison, among other most active developing countries, China performed 14 per cent of the transformation events, South Africa did 13 per cent, Argentina 10 per cent, and India also had 10 per cent. However, the success of such programmes would be indicated by the number of transformants that are actually registered for commercial release. In this regard, Indonesia is classified as being not as successful as other countries like China and India. In India, in 2003 commercial release application were made for 34 events, while in that same year the Chinese National Commission of Biosafety received 1044 applications for confined field trials.[17] Meanwhile, there was only one approval issued in Indonesia, and that permit was only valid for one year. The proponent had to renew the permit each year, but after three years elapsed, Monsanto decided not to extend it any further.

Research on transgenic plant constructions in Indonesia during the period of 1996-2004 are listed in Table 6. There were 20 different commodities being targeted for transformation, with several different introduced traits. But they were largely or mostly unsuccessful. Out of 31 different construction activities, only 16 of them were still active (going-on) and only two of these 16 actually resulted in application for for release approval. There were several reasons given by the researchers for these projects being terminated, such as lack of progress; termination of grants; *etc*. It would be interesting to look further into the actual cause of such low success rates of transgenic research in Indonesia. Was it caused by a lack of technology transfer or by a non-conducive research environment? Or was it because of limited and irregular fund availability?

There were several institutions performing transgenic constructions in Indonesia, such as government institutions whose mandate exclusively pertains to conducting research; universities; government-owned corporations; and private companies.[18] Government institutions with exclusive research mandates tend to have an easier time in getting research grants, but this is not the case with the universities, whose main mandate is education. Consequently, most research activities in the universities have a shorter lifespan and rely heavily on competitive domestic grants like RUT and grants from overseas. Once the funding is terminated, research activities associated with it will also cease to exist. A good example, of this unfortunate condition is found to be in the development of citrus resistant to CPVD and potatoes resistant to fungi/nematodes, which were the results of at least five years worth of research that cost between IDR 1.4 - 3.1 billion. These activities were simply terminated, because there was no funding available for the principal investigators to apply for the expensive and complicated regulatory process required for the approval. This clearly set a negative precedent for future developments of transgenic plants. On the other hand, a stringent regulation that complies with international standards is required to ensure the safety and health of the public and the environment. This is an absolute prerequisite in gaining public acceptance of genetically-engineered products, as also in the winning of acceptance from other countries of Indonesian agricultural products with genetic modifications (personal communication with the Director General of Food Crops, 2006). So how thorough should the evaluation process be? What types of tests need to be conducted? And who will foot the bill? These questions need to be considered before starting a research in developing transgenic plants, so that the result of all the hard works can be utilised by farmers and all Indonesian citizens in general.

The results of the surveys also indicate that priorities must be set to decide on which commodities will benefit most from genetic engineering. The priorities can be set by considering all the available information/data, both on technical and socio economical aspects. Socio economic assessment is needed (i) to get real beneficiaries of the transgenic plants; (ii) to get real benefit-cost involve in R&D activities; (iii) to get tolerance level; (iv) as a back up for policy direction on prioritisation; and (v) as a transparency tool for accountability of activities. Once the priorities are set, a commitment needs to be made so that resulting research activities would be guaranteed continuous funding and supportive research environment. The funding and required facilities can be obtained through cooperation with an appointed institution that is both competent and has a strong commitment to produce transgenic plants that can be utilised by farmers and consumers in general.[19]

Prospects and Challenges of the Applications of Transgenic Plants in Indonesia

In order to win public acceptance for transgenic plants and their derivative product for domestic uses or exports, a set of regulations that comply with international standards and guarantee the food, feed, and environmental safety is needed. Several regulations on this matter have been issued in Indonesia, from the ministerial level to Presidential Decrees. The regulations continuously evolved since their inception in 1996, in the form of Food Law and other kinds of regulations, until the publication of Government Regulation No. 28 (2004) on food safety of genetically-modified products and Government Regulation No. 21 (2005) on the biosafety of genetically-modified products.

On a global scale, the existence of regulations on biosafety and food/feed safety in different countries will improve the acceptance of transgenic plants by the majority of the population as long as those regulations have consistent implementation and are strictly enforced. This was partly responsible for significant increase of the plantation area of transgenic plants worldwide. There are several benefits that can be reaped from planting transgenic crops. Available scientific data suggests that transgenic crops have improved agricultural production, increased farmer income, and reduced the usage of pesticides.[20] This can be illustrated by the following points:

1. China has started planting the Bt-cotton since 1997. By 2004, the total plantation area of Bt-cotton has increased to 5.7 million hectares, which is roughly 65 per cent of the total plantation area for cotton. Bt-cotton produced 8-10 per cent more yield compared

to non-Bt cotton. There are also additional savings from reduced insecticide use, which was around US $ 94.10 per hectare. Chinese national income derived from Bt-cotton was US $ 1.1 billion in 2004.

2. Mexico began planting Bt-cotton in 1996. Farmers who planted the cotton gained additional income from US $ 113 per hectare to US $ 354 per hectare compared to farmers who did not plant the Bt-cotton.

In the case of Indonesia, farmers started planting Bt-cotton in seven districts in the Province of South Sulawesi in 2001. Monsanto, as a multinational company, could only obtain a limited permit that had to be renewed each year. However, Monsanto decided to stop selling the Bt-cotton (Bollgard) in 2003 due to various reasons. One among these was that it was not profitable for them. Cotton is one of the major raw materials for the textile industry, but 99 per cent of the domestic requirements for cotton in Indonesia were still imported. A study conducted by Siregar and Kolopaking (2002) showed that the net income of farmers planting Bt-cotton was IDR 1,386,706 per hectare (equal to US $ 138 per hectare) while the net income of farmers planting other varieties of cotton on average was IDR 765,299 per hectare (equal to US $ 76.5 per hectare). The difference extended to the labour used as well; farmers planting Bt-cotton used less labours compared to the farmers planting non-Bt cotton.[21]

The fact that the plantation of Monsanto's Bt-cotton was terminated has impeded the development toward widespread plantation of other genetically-modified plants. Until this paper was written, no other transgenic plants have been commercially released in Indonesia, even though there has been an increase in the type of plants and their area of plantation in neighbouring countries like China, India, and the Philippines.

In order to facilitate and accelerate the development of transgenic technologies in Indonesia, a regulatory apparatus that can be implemented easily, economically, and consistently is required so that public acceptance of transgenic plants can be further improved. A simple legal framework is essential and necessary. However, the regulation has to be based on an international standard, be founded on a solid scientific basis, and should be accompanied by clear operational and technical guidance so that it can be easily implemented. The regulation would be implemented by the Biosafety and Food Safety Commission

(BFSC) and BFSTT. The organisation should be composed of experts and decision makers from several government institutions and private sectors. The system/framework of the commission must be clearly defined to prevent it from impeding the implementation of the regulations. This study found that under the old regulation (the joint ministerial decree), the BFSC's membership consisted of 21 high-ranking government officials, who due to their busy schedules always had difficulty in scheduling a meeting among them. Since its inception, the BFSC has only held 3-4 meetings. The BFSC was assisted by the BFSTT in their decision-making processes. But actually, it was the BFSTT who ran the day-to-day operation of the regulatory system. The BFSTT is an *ad hoc* committee, whose membership consisted of experts from different scientific backgrounds. It does not have a full time secretary for its daily operations. Its activities are scheduled according to the number of applications received by the technical team, and are mostly funded by the proponent/applicants. Each member of the BFSTT also had many other commitments so they often had difficulties in attending to their duties as Member of the Biosafety and Food Safety Technical Team. To illustrate this, it took the BFSTT less than one year to give approval to Monsanto's Bolgard cotton, but it took more than two years for the BFSC and the Minister of Agriculture to issue the permit even though the plant in question had already been certified as safe by the BFSTT.

This study also found that the BFSTT has not issued a standard (a SOP) on what kind of tests would need to be performed for evaluating the release of transgenic plants. For example, is it really necessary for different types of transgenic plants like the drought-resistant sugarcane (PTPN XI), Bt-rice resistant to stem borer (IIS), and potatoes resistant to fungi/nematodes (BAU) to supply all the information/data listed in Table 17?

Any existing regulations must clearly state whether data on food safety obtained overseas was also applicable in Indonesia, so that transgenic plants that have been released in other countries no longer need to be subjected to in-house data collections. Similarly, what kind of environmental impact assessment was necessary for plants that have been released in other countries and those that have never been released anywhere in the world? What kinds of parameters need to be measured in an environmental impact assessment? The applicants can carry out a food safety and biosafety evaluation according to the requirements set by the law/regulation once these issues are clear so that, there will not be any dispute or ambiguity when the information/data obtained from the evaluation process does not meet the required standards. For example, in an impact study on non-target insects, what kind of non-target insects would need to be evaluated? Or which soil would microbes need to be studied? Such details would need to be worked out because they would influence the cost of the approval process (without any disregard to the scientific/evaluative aspects). Ideally, the only information/data that need to be gathered in-house are those that have not been evaluated anywhere else, while data that are already available should not be gathered by *in-house* experiments. Any additional in-house experiments that may need to be performed should be done to answer standard questions set by the regulations for commercial release.

Endnotes

[1] James (2003).
[2] ISAAA (2005).
[3] Moeljopawiro and Falconi (1999); Bahagiawati *et al*. (2003).
[4] Pray *et al*. (2005; 2006).
[5] Moeljopawiro and Falconi (1999); Bahagiawati *et al*. (2003).
[6] Wirawan IPG (2000; 2004).
[7] Murdiyatmo *et al*. (2004).
[8] Bermawie *et al*. (2003).
[9] Halos (2006).
[10] Pray *et al*. (2005).
[11] Pray *et al*. (2006).
[12] Dedi Fardiaz (2006), personal communication).
[13] ISAAA (2005).
[14] Pray *et al*. (2006).
[15] Halos (2006).
[16] Atanassov *et al*. (2004).
[17] Pray *et al*. (2006).
[18] Moeljopawiro and Falconi, (1999); Bahagiawati *et al*. (2003)
[19] Personal communication with the Director General of Horticultures, 2006.
[20] Graham and Barlofoot (2005).
[21] Lokollo (2001).

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