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The Economy and Environment Program for Southeast Asia (EEPSEA) was established in May 1993 to support training and research in environmental and resource economics across its 10 member countries: Cambodia, China, Indonesia, Laos, Malaysia, Papua New Guinea, the Philippines, Sri Lanka, Thailand, and Viet Nam. Its goal is to strengthen local capacity for the economic analysis of environmental problems so that researchers can provide sound advice to policymakers.

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# Making Biotechnology Safer: An Assessment From The Philippines

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Modern biotechnology is one of the most controversial areas of scientific development. It has been championed as a solution to poverty, hunger and environmental degradation. However, there are also many environmental, health and social equity concerns associated with the genetic modification of crops and animals. The challenge, ➡

A summary of EEPSEA Research Report 2005-RR13, *Biotechnology Product Development, Biosafety Regulations and Environmental Risk Assessment in the Philippines* by Linda M. Peñalba, John A. Fajardo, Flordeliza A. Sanchez and Aida O. Grande. Address: Institute of Agrarian and Rurban Development Studies, College of Public Affairs, University of the Philippines, Los Baños. Email: [lendz27@laguna.net](mailto:lendz27@laguna.net).

# “Policy makers should balance regulation...

→ particularly for developing countries, is to benefit from these technologies while ensuring that biosafety issues are adequately addressed.

A new report from the Philippines looks at how the country is placed to meet this challenge. It finds that, due to limited resources, the amount of biotechnology research done is limited. It also finds that biosafety regulations are relatively good. Both areas, however, need support and investment. Overall, the report calls for the Philippines to carefully balance the need for biotechnology regulation with the need for innovative biotechnology development.

## Regulation And Development

The study was undertaken by Linda M. Penalba, John A. Fajardo, Flordeliza A. Anchez and Aida O. Grande from the Institute of Agrarian and Rurban Development Studies at the University of the Philippines, Los Baños. Limiting their study to the biosafety regulation of GM crops, they looked at the prospects for biotechnology product development (BPD) in the Philippines. They also set out to see whether the country's biotechnology organisations are in a position to effectively perform biosafety regulation, protect intellectual property rights and respond to the accelerating pace of biotechnology product development.

The study was conducted against a

Annual budget released for agricultural biotechnology R&D, 1998-2005.

YEAR	Funding Source (in Million Pesos)		Total
	BAR	PCARRD	
1998	*	0.9	0.9
1999	10.4	17.8	28.2
2000	11.9	8.0	48.1
2001	3.6	5.3	8.9
2002	4.6	2.3	6.9
2003	1.0	2.7	3.7
2004	0.6	*	0.6
2005	*	1.0	1.0
Total	32.1	38.0	70.1

BAR: Bureau of Agricultural Research

PCARRD: Philippines Council for Agriculture, Forestry and Natural Resources Research

background of growing levels of biotechnology research and implementation. Between 1996 and 2004, the global area of transgenic crops increased 47-fold, from 1.7 million to 81 million hectares. This rise was particularly notable in developing countries, where adoption rates increased by 35% in 2004 (compared to only 11% in the industrialized countries). Nine of the fourteen biotech "mega-countries" (those growing 50,000 hectares or more of biotech crops) are in the developing world (the Philippines being one of these).

Despite expectations that biotechnology can enhance crops and reduce environmental damage caused by agricultural chemicals, there are many concerns about GM crops. These include the possibility that transgenes will escape from cultivated crops into wild relatives and that allergens will be introduced into food. These concerns are heightened in developing countries, which often have weak testing and regulatory capacities. There are also concerns that this technology does not meet the needs of the poor and that poor countries cannot afford the research and development budgets required to fully capitalise on this

technology. Moreover, many developing countries cannot adequately protect the intellectual property rights of technology developers – another disincentive for investment.

## Assessing The Local Situation

The researchers used both primary and secondary data. Primary information was gathered through interviews with key informants from state colleges and universities, public research and development (R&D) institutions, and other agencies, commercial operations and individuals. Secondary information was gathered through a review of biotechnology and biosafety reports and other relevant documents.

Interviews were conducted to validate information and to assess the applicability and relevance of the principles and concepts proposed in the policy analysis. The preliminary findings of this study were presented to scientists and policy makers in a round-table discussion to validate assumptions, conclusions and recommendations.

The prospects for biotechnology product development in the Philippines were assessed by analyzing public and

# and promotion of biotechnology.”

private R & D initiatives and public investment in agricultural biotechnology R & D. The effectiveness of the Philippine Biosafety Regulation System (PBRs) was assessed by comparing the Philippine Biosafety Guidelines (PBG) with selected biosafety regimes in developed and developing countries. The PBG was also assessed against the Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity (CBD). This is an international legally-binding instrument on biosafety.

In addition, an assessment was made of the bio-safety regime for Bt corn event MON 810. This is the first genetically-modified crop approved for commercial release in the Philippines. It is also the first biotechnology material that has so far gone through the entire biosafety regulation process. Bt corn contains a gene that confers resistance to Asiatic Corn Borers.

The study also analyzed the laws affecting intellectual property (IP) management and the IP safeguards that have been instituted in the Philippines.

## A Practical Approach To Biotechnology

Biotechnology research and development institutions in the Philippines take a practical stance in the prioritization of research projects. Their R & D efforts are largely focused on the local testing of technologies developed in other countries, rather than on basic research. This is because local testing of patented technologies does not impose huge technology or product development costs and yields immediate results.

The prospect for biotechnology product development in the Philippines is largely constrained by low and poorly-sustained levels of investment by the public and private sectors. For example, from 1998 to 2005, a total of forty projects were supported by the two government funding agencies. These had a total budgetary requirement of PHP 103 million. However, only PHP 70 million was actually released.

Other problems include lack of coordination among agricultural R & D institutions, and the limited capacity of local institutions to undertake state-of-

the-art R & D. From 1990 to 2004, only eight public institutions, thirteen private institutions and about 110 scientists were involved in the government's agricultural biotechnology R & D projects.

Results of the PBRs comparison show that biosafety guidelines in the Philippines are as stringent as those of other developing countries (Indonesia, Malaysia, Vietnam, Mexico and Norway) and developed countries (USA and Japan). Efforts to make the regulatory system consistent with the Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity are also underway.

## Safer Corn?

In accordance with the Philippine Biosafety Guidelines, the biosafety assessment of Bt corn underwent four stages between 1996 and 2002: glasshouse trials; limited field trials; multi-location field trials; and before commercialization in 2002. It took more than six years for MON 810 to be approved for commercial release. The long risk assessment process and the meticulous risk assessment procedure reflect the commitment of the National Committee on Biosafety of the Philippines (NCBP – the main regulatory body) to ensure biosafety, even if the biotechnology product being tested is already widely adopted in other countries.

Weaknesses in the country's biosafety program included a number of functional problems within its Institutional Biosafety Committees. These are a critical part of the entire risk assessment process. It was also found that scientists who work with the NCBP are undervalued and poorly paid. Moreover, the NCBP operates on a

Biosafety guidelines in various countries

Areas	PH	INDONESIA	MALAYSIA	VIETNAM	JAPAN	NORWAY	USA	MEXICO
Use of existing legislation								
Mandatory pre-market approval	✓	✓	✓	✓	✓	✓	✓	✗
Established safety standards								
Transparency (reg. process)	✓	✗	✗	✗	✓	✓	✓	✓
Transparency (data)	✓	✗	✗	✗	✗	✗	✓	✗
Public information (applicant)	✓	✗	✗	✗	✗	✓	✓	✗
Use of outside consultants								
Post-approval activities	✓	✗	✗	✗	✗	✗	✓	✗

✓ = present ✗ = weak or absent

very small budget that has declined from about PHP 500,000 (approx. USD 20,000) in 1991 to only PHP 160,000 (approx. USD 3,000) in 2004. A realistic budget for NCBP would be about PHP 5 million (USD 100,000) per year. This could cover all the operational expenses of the government agencies involved in the implementation of the PBG.

It was found that the law that best provides IP protection for biotechnology products and processes is the IP Code. This specifies that micro-organisms, non-biological processes, and micro-biological processes used for biotechnologies can be patented. However, it was also found that no mechanism to monitor any infringements of biotechnology IPRs has yet been installed.

## What Should Be Done?

Because of the budgetary constraints they operate under, Filipino scientists should focus on studies that do not require significant resources but which can contribute significantly to biosafety in the country. The report provides a list of such studies - for example, investigating the appropriate risk assessment protocols and the potential long-term effects of Bt corn.

To address funding shortfalls, R & D institutions should negotiate better terms with the commercial organizations that will benefit from the release of GM products in the Philippines. They should look beyond the actual cost of conducting the experiments and study the feasibility of getting a share of the potential sales revenue.

To sustain the effectiveness of the PBRs, realistic budgets need to be allocated to the agencies involved in biosafety regulation. Risk assessment principles and procedures need to be institutionalised. To improve the functioning of the Institutional Biosafety Committees (IBCs), the National Committee on Bio-safety of the Philippines should monitor them more closely and set up an IBC Secretariat.

Two biosafety regulation measures can be used to protect IP holders against fraudulent IPR claims. These are (a) the use of information on DNA constructs filed at the NCBP; and (b) the use of genetically-modified organism detection kits.

## The Future Of Biotech In The Philippines

Overall, the report calls for policy makers

to carefully balance the need for regulation with the need to encourage innovative biotechnology development. On the one hand, excessive regulatory reviews may curtail interest in biotechnology R & D. It may also mean that only a few large multinational companies will have the necessary resources to go through the entire process. Therefore, over-regulation may promote the corporate control of agriculture. On the other hand, relaxed regulations that allow rapid and easy approval of GMOs may not effectively protect citizens and the environment from potential risks.

Looking ahead, considering the global and local trends in agricultural biotechnology R & D, the biosafety challenge will become ever more important and require increasing levels of governmental support and finance.

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