Experiences of the Philippines:
Implementation of Cartagena Protocol and Good Practices on Biosafety Information

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Sharing

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Outline

- *Philippines Biosafety Regulatory
 Structure
- * Cartagena Protocol on Biosafety
- * Article 20: Biosafety Clearing House
- * Article 23: Elements of Public Awareness and Participation
- * Philippines Experiences in implementing Article 23
- * Updates on other Provisions of the Protocol



In the Philippines

- 1987 Concerns on safety of researches in modern biotech took center stage when DNA technology was used to improve plants, animals and microorganisms
- Creation of a Joint Committee
- Formulation of guidelines for R&D of UPLB and IRRI
- Initiative was adopted nationally by issuance of E.O. 430



Biosafety regulation of GMOs

- 1991 Establishment of the National Biosafety Committee (NCBP)
- Oversee compliance with biosafety policies and guidelines being implemented by the regulatory agencies of the government
- Multi-agency scientific/technical body (regulatory agencies, 4 scientists, 2 community representatives)



The need for Biosafety regulation of GMOs

- We need a Framework within which we can assess the safety of the products of modern biotechnology
- Based on the safety assessment, the government can approve of refuse entry of GMOs into the country
- Since GMOs are Living Modified
 Organisms in the form of plants, animals
 or microorganisms they
 can impact on the environment and
 human health







Biosafety REGULATIONs are in place prior to the Philippines' signing of CARTAGENA Protocol on Biosafety in 2000

October 16, 1990: Biosafety Regulatory system was established (the 1st in Asia)

Operational Guidelines:

Philippine Biosafety Guidelines ,s 1991 Planned Release Guidelines for GMOs and PHES

April 2, 2002 DA A.O. 8: Field testing, Propagation and Use of LMOs for food, feed and processing

Stages in the development of GMOs requiring regulatory approvals

Experimenta

 Contained use (laboratory, greenhouse, screenhouse)

Confined test

(NCBP: 1990 to 2003)

(DOST Biosafety Committee: 2008 to present)

Risk Mitigation

- Large Scale release (Single/multi sites testing)
- Commercialization)
- Use for Food, Feed and Processing

((NCBP: 1990 to 2003)

DA-BPI Biotech Core team: 2002 t

Risk Assess

March 16, 2006: National Biosafety Framework

* Expands the scope of E.O. 430 to include other government agencies, scientists and non-government groups

Preparatory to extended genetic engineering activities to include **not only crop plants** but also livestock, microorganisms and other species; not only for food and feed but for pharmaceuticals, nutraceuticals, bioremediation agents and other types of GMOs

- Delineates the responsibilities of the regulatory agencies
- * Strengthen the existing science-based determination of biosafety
- * Guidelines in implementing the Cartagena Protocol

PHILIPPINE BIOSAFETY ORGANIZATIONAL STRUCTURE

BCH Pilipinas (The Philippine Biosafety Clearing-House) National Committee on Biosafety of the Philippines

Executive Committee (optional)

TWG (optional)

DOST Biosafety Committee: Contained, Confined Experiments of GMOs (Laboratory, Screenhouse, Greenhouse, Glasshouse, Confined Test (CT))

IBCs

DENR Biosafety Committee:

Planned Release of GMO (including CFT of GMO endorsed by DOST-BC) and Propagation/Production:
Bioremediation Products, Forest Genetic Resources, Wildlife Genetic, Aquatic & Terrestrial

IBCs

DOH Biosafety Committee:

Planned Release of GMOs
Pharmaceuticals (including CFT of GMO endorsed by DOST-BC) and
Propagation/Production: Health Impact Assessment; Safety & Efficacy GM Pharmaceutical Plant; Evaluating Processed food derived from modern biotechnology

DA Biosafety Committee:

Planned Release of GMO (including CFT of GMO endorsed by DOST-BC) and Propagation:

Plant and Plant Products, Domesticated animals, Biological products for animal husbandry & veterinary purposes, Fisheries and other Aquatic resources, Biocontrol agents, Food, Feed and Processing

BCs

STRP

IBCs





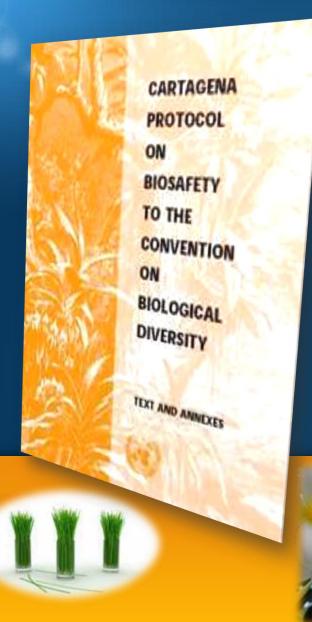
IRRI CL4 facility

APPROVALS

Contained experiments and Confined Tests: 215

Commercialization/Direct Use: 58





Philippines Membership to the Protocol

- Instrument of ratification signed in November 2000
- Concurred by the Philippine Senate on **August 14, 2006**
- Entered into force on January 8, 2007



Philippine obligations as Party to the Protocol

Becoming a Party to the Protocol also confers a number of obligations, among which is:

- ☐ Information-sharing and reporting requirements.
- Cooperation with other states and international bodies to promote and facilitate Public Awareness and education, including access to information, regarding the safe transfer, handling and use of LMOs.
- ☐ Consult the public in the decision making process, make public the final decision taken and inform the public about the means of access to the BCH









Public Awareness, Education and Participation: Article 23

Executive Order No. 514

Section 1: Constitutional Policies

1.9: Right to participation: The right of the people and their organizations to effective and reasonable participation at all levels of social, political and economic decision-making shall not be abridged. The state shall, by law facilitate the establishment of adequate constitutional mechanism (Article XIII, Section 16)

The country has established strategies and guidelines for the conduct of meaningful, responsible and accountable public awareness, education and public participation to promote the NBF. The programme includes:

capacity building, public awareness and education, public access to information, and public participation



NBF: Section 6: Access to information

- **Disclosure of information**, subject to reasonable limitations to protect Confidential information, in a prompt and timely manner
- Access to biosafety decisions (summary of applications, result of risk assessment and other relevant information)
- Access to information related to risk management, product monitoring and product identification



CONFINED TEST

- The applicant, through its IBC, shall notify and invite comments on the field testing proposal from the barangay and city/municipal governments with jurisdiction over the field test sites
- Posting of DOST-BC approved
 PIS for two consecutive weeks
- Proof of Posting: Certification from local Barangay official

Requirements for Field Testing, Propagation and for Direct Use as Food, feed and processing

- Publication of PIS in two newspapers of general circulation
- 30 days comment period
- Written comments
- Proof of publication within 15 days from date of publication

Department of Agriculture Administrative Order No. 008 (DA A.O. 008).

Section H: Public hearing

"If based on the report of the STRP, the proposed release may pose significant risks to human health and the environment, the Director of the BPI shall cause the IBC to conduct public hearings within the vicinity of the proposed filed test sites within 30 days from the date the application was furnished the BPI a copy of the report."







Department of Agriculture Administrative Order No. 008 (DA A.O. 008). Section 10: Requirements for Release for Propagation

Other requirements:

- Identification of Imported regulated article: importation document should state that he importation may contain GMOs;
- Approval registry for propagation BPI established and maintain registry of approved regulated articles for propagation



Public Access to Information: Biosafety Clearing House (Article 20 of the Protocol)

- UNEP-GEF Project entitled "Effective Participation on the Biosafety Clearing House of the BCH" (BCH I Project) for the setting up of the Philippine BCH (2008-2009).
- Creation of a BCH Task Force
- Development and establishment of a BCH Website
- Development of coordination mechanism for uploading data into the BCH



In support of transparency and public participation, BCH was established in 2007" Maintained/admnistered by NCBP/DOST Biosafety COmmittee



What is the Role of the BCH?

Capacity-building Roster of Experts

Information Sharing

National Reports

Search Feature

Resources

Site man

- (a) To facilitate the exchange of scientific, technical, environmental and legal information on, and experience w living modified organisms; and,
- (b) To assist Parties to implement the Cartagena Protocol on Biosafety.

What is the Cartagena Protocol on Biosafety?

BCH II

Continued Enhancement of Building Capacity for Effective Participation in the BCH Project Duration: June 2011 to April 2012)

- Workshops
- Promote capacity-building activities at the global, regional and sub-regional levels, increase levels of understanding and exchange of experiences among different countries;
- Produce further guidance on the BCH for various target stakeholders

UNEP-DELC-GEF Project for Continued Enhancement of Building Capacity for Effective Participation in the BCH (BCH-II Global Project)



The Philippine Biosafety Clearing-House National Workshop











BCHII

(June 2011 to April 2012)

> Workshops:

- > for the CNAs: filling up of common formats, registering records, publishing information
- For custom officers, phyto sanitary regulators inspectors, media, civil society & other stakeholders: Familiarization with handling and transport procedures, documentation of shipments and use of barcode in shipments,
- For Media, educators, civil society, industry reps how information in the BCH can be accessed and utilized. Media, educators, civil society reps Training materials were introduced for use of the participants in their IECs activities.

BIOSAFETY CLEARING-HOUSE OF THE PHILIPPINES

To intensify the efforts of ensuring public awareness on biosafety of GMOs and fostering of international linkages, the Philippines signed the Cartagena Protocol on Biosafety and became a Party on 24 May

2000. In compliance with Article 20 of the Protocol, the country set up the Biosafety Clearing House (BCH) in 2008 which was later popularized with the brand "BCH Pilipinas".









The BCH Pilipinas is an online portal that serves as a 'one-stop shop'where users can easily search and retrieve biosafety-related information. It forges collaboration among regulatory agencies and their partners in extending information services for the



benefit of public and private research institutions, civil society organizations, and other stakeholders involved in biosafety.

Information available in the BCH Pilipinas includes pertinent policies and regulations governing GMOs; risk assessments and country decisions





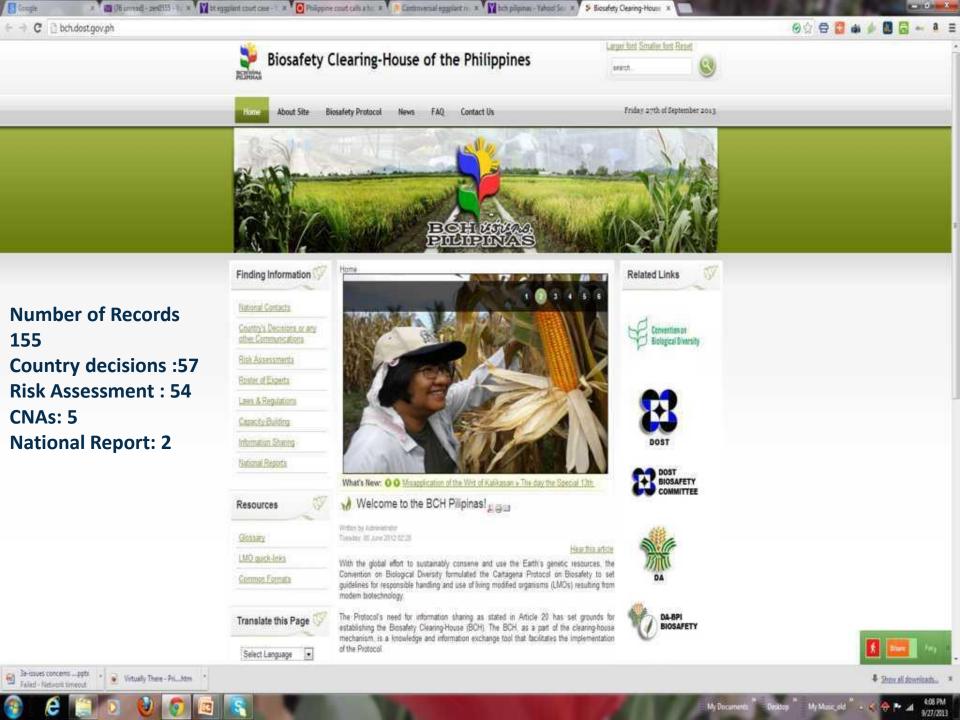




The Philippines thru the BCH Project was able to:

- Provide greater awareness on the obligations of a Party to the Protocol, implementation of its provision and in ensuring the safe movement of the products of GMOs across countries.
- Introduce the features and functionality of the BCH Central portal and how the various information regarding GMOs can be used by various sectors of society for whatever purpose it will serve.





Capacity Building: Article 22

- Parties shall cooperate in the development/strengthening of human resources and institutional capacities in biosafety, including biotechnology....... Through global, regional, subregional and national institutions and organizations, and through facilitation of private sector involvement
- Scientific and technical training in biotechnology management, risk assessment and managements and enhancement of technological and institutional capacities.



Capacity Building: Article 22

- Workshops in Environmental Risk Assessment
- Principles, Methods and Information Resources for Environmental Risk Assessment of Transgenic Crops
- Communicating biosafety
- Send regulators to MSU Courses, Training of Trainors, Certificate Program in Biosafety and Applied Plant Biotechnology in the US









Public Awareness and Participation: Article 23

Has been going on since 1987: consultations on the technology and biosafety guidelines, prior to the first field trial (MON810) in 1999 up to the present







Public Awareness, Education and Participation

- 1. Outreach Program (Seminars/Fora)
 - Public, Consumers, Students
 - Officials and Employees of National and Local Government Units
 - Legislators (Congress, Senate)
 - Members of the Judiciary
 - Farmers and rural communities
 - Religious Orders
 - Science community
 - Regional Offices Employees and Officials of the Competent National Authorities
 - Mass Media

Public Awareness, Education and Participation

The activities are focused on the following:

- Basic concepts of agricultural biotechnology, global status of biotechnology, R&D activities adoption of commercialized GMOs in the country
- Biosafety Regulatory system
- Assessment of the potential risk of GMOs to health and the environment
- Food Safety Assessment
- ☐ Risk Management and Risk Communications
- Biosafety Clearing-House and its features
- Exhibits, Round table discussions, Print and broadcast, Annual celebration of National Biotechnology Week











Public Awareness, Education and Participation

PROVINCES THAT ISSUED ORDINANCES BANNING gmoS

BOHOL Three resolutions and One Ordinance:

2003 and 2010

Mindoro Oriental MC and Ordinance: 2004 and 2005

Negros Occidental Ordinance: 2007

Negros Oriental Ordinance: 2010

Municipal of Sta Barbara Iloilo: Resolution: 2010

LOBBYING FOR ANTI GMO POL CY issuances

ANTI GMO Campaign

A well-funded, well organized campaign that started in Europe in mid-1990's, and has since spread to all countries; Stemmed from insufficient information about GM crops STRATEGIES:

Multi media mis-information campaign based upon myths and false representation, use of scary tales and Sows fear of GM products, relentless misinformation – internet and press releases

Use of poor or bad science
Destruction of field trials
Lobbying Policy Makers
Filing of Court cases

The Anti-GMO Campaign: Saturnina Halos, Ph.D.



ANTI GMO Campaign

Bt Corn Trial Anti-GM Uprooting in Tampakan, South Cotabato (August 29, 2001)







ANTI GMO Campaign

Bt Corn Trial Site Failed Uprooting Attempt in Kibawe, Bukidnon (Sept 4, 2001)









Filing of Court Case late April 2012: Bt Eggplant Legal remedy VS GMO invasion sought

Greenpeace files a Writ of Kalikasan asking Supreme Court to stop the Bt Eggplant field trials



OMO Ban Potition in the Philippines E

VI Villafrança / Dreenpeace



The Supreme Court ruled unanimously that GE Bt egoplant violates the public's constitutional rights to a healthy environment and therefore recognized the scientific ancertainties of the health and anvironmental safety of SE Bt appoint. It ordered the respondents, including the Department of Environment and Natural Resources, to justify the field testing of GE BE eggplant in the country within the next 10 days.

engineered organisms (GEOs). This landmark

decision will become subject to national and

international legal discourse in years to come

The petitioners had filed a writ of kalikasian, which is a unique Philippine legal remedy for people whose constitutional right to a balanced and healthy ecology is violated or threatened by an unlawful act or omission of a public official, involving environmental damage of such magnitude as to prejudice the life, health or property of enhabitants in two or more closs or

in seeking the writ, the pottioners highlighted the need to first ensure the safety of GE Bt. egoplant on health and environmental grounds before it is released into this point through field

The petitioners also asked the court to halt all GE Bt ecoplant field trials in the country on the basis of scientific uncertainties of the GE technology and the questionable regulatory process. Currently, regulators are approving almost 100% of all GE applications, which brings into question whether the applications are properly sorutaised before approval.



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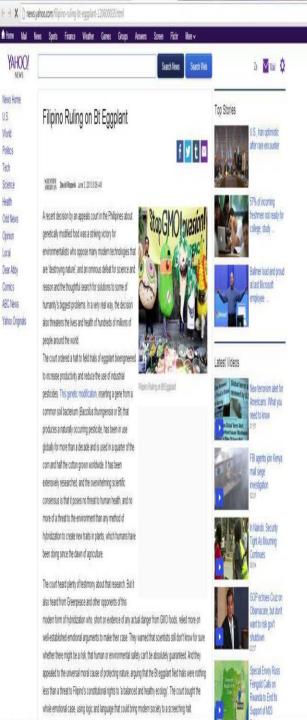
Things you can do now

- · Se an ocean defenden
- Stop GNO field trials in the Philippines
- Tweet for sustainable agriculture
- Fundraise for Greenpeace
- · Get evolved with the Water Patro
- Become an onime activist Donate I breet a day
- Support our work

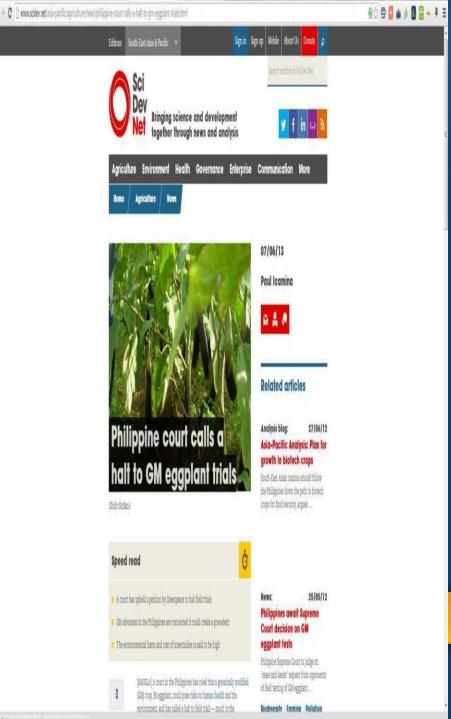
issues we work on

i Climate Change

- Sustainable agriculture - null



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• A court in the Philippines has ruled that a genetically modified (GM) crop, Bt eggplant, could pose risks to human health and the environment, and has called a halt to field trials — much to the disappointment of researchers.

The Philippine Court of Appeals said there is a lack of "full scientific certainty" and has ordered that scientists "permanently cease and desist" from further conducting Bt talong field trials the trials".

 Respondents appealed the decision with the higher court.



National Committee on Biosafety of the Philippines

Issues raised by ANTI GMO

Technological Issues:

- Super weeds
- Superbugs
- Effects on Non-target organisms
- Genetic Contamination (Gene flow from GM corn to Ordinary corn = we eat the gene in the contaminated corn
- Horizontal Gene Flow
- Contamination of organic crops (Co-existence is impossible)



Issues raised by ANTI GMO

Ethical Issues

- Tinkering with nature
- Playing God
- Biotechnology causes commodification

Socio-economic Issues:

- Access to Intellectual Property Rights
- Multi national Corporations will control the production of GM crops
- Access to technology: higher cost







Taken from: The Anti-GMO Campaign: by Saturnina Halos, Ph.D.















Consultation on various agenda and issues on COPMOP IV

BSWM-Quezon City; April14,2008



National Committee on Biosafety of the Philippines



Public Consultations on the Manual on Biosafety Decision—Making Process under E.O. 514

16 January 2012 (Taguig City); 31 January 2012 (Quezon City); 16 February 2012 (Davao City); and 15 March 2012 (Cebu City)









Study Group Tour for the "Water Efficient Maize For Africa (WEMA)" DOST Conference Rm., Bicutan, Taguig City, 18
September 2009



Visit of
Bhutan Agriculture and Food Regulatory
Authority (BAFRA) <u>2012-December 3-5</u>
Focus is on biosafety regulation and BCH



Communication Plan for 2014

In addition to the IEC activities undertaken in the last decade, the following shall be conducted:

ACTIVITY	TOPIC	PARTICIPANTS	
Exhibit Cum Forum	Biosafety Regulations Cartagena Protocol	Members of the Judiciary, (Greening the bench), Legislators Employees and Officials of the Local Government Units	
Seminars with Exhibits	Biosafety Regulation Cartagena Protocol	national government executives, association leaders, scientists, educators and advocacy leaders	
Orientation Seminars	Biosafety Regulation Cartagena Protocol	producers, consumers, media and the general public	

Article 27 Liability and Redress

- ☐ Deferred the accession to the Protocol
- ☐ Harmonize the existing domestic laws to address damage
- ☐ CNAs to review their existing response measures on liability and redress.

Article 26 Socio-economic Considerations

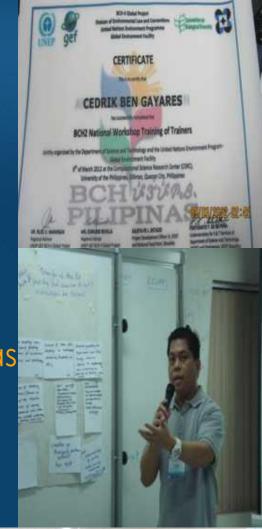
- □Socio-economic considerations should not be a requirement in conducting risk assessment, which should remain scientific and technical in nature.
- □SEC could be taken into account in crafting risk management strategies to appropriately address the concerns of indigenous and local communities.
- De used in determining the socio-GMOs, but does not support prescriptive guidelines that will impede the development of crops that are important to the country.

Articles 15 and 16 Risk Assessment and Risk Management

- ☐ the country acknowledges the draft "Guidance Document on the Risk Assessment of Living Modified Organisms" in the risk assessment paradigm
- Recommends the development of a general document, instead of crafting several sub-documents for each type of LMO that will be developed in the future.
- □ During COP/MOP 6, the country withheld its endorsement on the adoption of the guidance document with the contention that it still needs further refinements and actual testing by the countries and independent experts with actual experience in
 - risk assessments.
- supports the continued existence of the AHTEG with an expanded membership to include Parties with experience in risk assessment

Challenges:

- Have yet to upload decisions on field testing (1999 to present)
- Modify records of biosafety experts due to change in format
- Work on the yearly budget and permanent staff
- Continuous improvement of BCH Pilipinas making it more user-friendly in response to the comments and inputs of participants during the BCH Training Workshops





CHALLENGES IN THE BIOSAFETY REGULATORY SYSTEM

- > Harmonization of the existing guidelines of the agencies involved in biosafety regulation
- > Creation of a permanent office that will coordinate with the Competent National Authorities on matters pertaining to biosafety
- > Strengthening of IEC initiatives (Insufficient information/briefing materials, Busy schedule of NCBP/DOST-BC and CNAs' personnel hinders them from adequately addressing IEC needs on biosafety)

CHALLENGES IN THE BIOSAFETY REGULATORY SYSTEM

- > Increase of budgetary allocation to adequately carry out the mandates of the respective agencies to implement E.O 514
- > Further capacity building especially of the regional monitors
- > Insufficient government support, i.e. financial and administrative, for modern biotech researches



☐ The public will accept biotechnology only when individuals decide for themselves that GM crops and food products will contribute to their personal well-being. To make such a decision, ordinary people will need greater awareness and understanding of how biotechnology will affect the environment, human health, local and national economies, and the well-being of society.

Also key to public acceptance is the establishment of a functional regulatory system having legitimate authority to control use of the technology, and public awareness that such a system operates to protect the environment and human and animal health.

Reference: TRAYNOR, Patricia L.; ADONIS, Marta and GIL, Lionel. Strategic approaches to informing the public about biotechnology in Latin America. *Electronic Journal of Biotechnology* [chline]. 15 April 2007, vol. 10, no. 2 [cited date]. Available from:

http://www.ejbiotechnology.info/content/vol10/issue2/full/12/index.html

ISSN 0717-3458. **DOI:** 10.2225/vol10-issue2-fulltext-12



NCBP:

http://www.ncbp.dost.gov.ph Files from 1991 to 2009 Contained use and field tests (1999-2002)

DOST Biosafety Committee:

dost-bc.dost.gov.ph Proposals for contained use from 2009 to present

Department of Agriculture

http://www.da.gov.ph

BCH Pilipinas:

http://bch.dost.gov.ph









Thank You







