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## Philippines

## Biotechnology

## Annual

## 2007

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**Report Highlights:**

Philippine market acceptance of GE crops and their products will increase upon the commercialization of the first locally developed GE crop sometime early 2009. Being a growing net-food importer, while adjustments in local biotechnology regulations are imminent in view of international developments governing trade, the resulting regulatory refinements are expected to be practical and appropriate within the bounds of sound science.

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Includes PSD Changes: No  
Includes Trade Matrix: No  
Annual Report  
Manila [RP1]  
[RP]

## I. Executive Summary

The Philippines is a growing net food importer with total agricultural imports increasing about 9 percent annually since 2004. Last year, the Philippines was the 15<sup>th</sup> largest export market for US agricultural, fishery and forestry products, with overall export value increasing by 16 percent, reaching \$924 million from the \$826 million in 2005. During the same period, the Philippines was our 3<sup>rd</sup> largest soybean meal market, 5<sup>th</sup> for dairy products, 6<sup>th</sup> for snack foods excluding nuts, 4<sup>th</sup> for wheat, 12<sup>th</sup> for pet food, and 15<sup>th</sup> for consumer-oriented agricultural products.

Under the current biotechnology regulations provided for under the Department of Agriculture's Administrative Order No. 8 (DA-AO 8), 25 transformation events (TEs) and 15 combined or stacked trait products have been approved for direct use as food, feed or propagation. Guided by DA-AO 8, the first GE crop being developed locally will likely be commercialized by early 2009. Other GE research projects are expected to follow shortly. This bodes well for the positive prospects of future market acceptance of GE crops and its derived products.

Nearing its 5<sup>th</sup> year of existence, regulatory refinements of DA-AO 8 are imminent and largely evolutionary in nature. Recent international developments including the country's accession to the Cartagena Protocol on Biosafety (CPB), and the ongoing discussions in Codex Alimentarius Commission's Biotechnology Task Force on Adventitious Presence (AP), are also driving regulatory adjustments. In general terms, the resulting regulatory system is expected to be more practical, while remaining science-based.

## II. Biotechnology Trade & Production

In 2006, the Bureau of Plant Industry (BPI) estimates the total area planted to GE crops at roughly 100,000 hectares, almost double the estimated 50,000 hectares planted the previous year. GE crops planted last year were all corn varieties consisting of Bt corn (75,000 hectares); roundup ready corn (26,000 hectares); and the combined roundup ready and Bt corn variety (4,000 hectares). The area estimates are based on local seed sales of domestic seed companies. The increase in GE corn use likely enhanced overall corn production in 2006, exceeding 6 million MT for the first time in history. The total area planted to GE corn last year is less than half of one percent of total national area planted to the grain, and represents very positive prospects for increased GE corn use in the next 3-5 years. High and increasing world corn prices complements this scenario.

As mentioned in GAIN 6026, the delayed ripening papaya project being developed by the Institute of Plant Breeding of the University of the Philippines at Los Banos (IPB-UPLB) will likely be commercialized only in 2010. This project was granted field-testing approval early this year (see Table 1). The papaya ringspot virus resistant project, on the other hand, has completed its contained trial (greenhouse) and recently obtained its certificate of completion from the National Committee on Biosafety of the Philippines (NCBP). According to the IPB-UPLB, confined field trial (outside greenhouse) commenced February 2007 and multi-location trials are tentatively set to begin early next year. All regulatory requirements, including food safety assessment and seed bulk-up, are likely to be completed by 2009 with its commercial release expected by the first quarter of 2010.

For the fruit and shoot borer resistant eggplant, the project completed its contained trial and is currently awaiting the issuance of certificate of completion by the NCBP. Confined field trial has been applied for and will likely commence in August 2007, according to the IPB-UPLB. The Maharashtra Hybrid Seed Company of India, the developer, has made available to

IPB-UPLB the biosafety and food safety data for the Bt event to expedite regulatory compliance. Commercial release is expected by the first Quarter of 2009.

The Philippine Rice Research Institute (PhilRice), which is working on its golden rice (GR) project, reports that as of mid-2007, introgression work has so far produced several BC2F1 populations, and are currently being evaluated using molecular markers. The level of beta-carotene in some of the progenies will be measured starting this season and by the end of this year, BC2F1 and BC2F2 populations are likely to be produced. The PhilRice expects field experiments to begin first half of 2008 should there be no regulatory constraints.

The PhilRice adds that for the other aspect of the project, BC4F1 populations have also been produced from various crosses. Selected populations will be planted and evaluated for presence of the GR trait and will also be subjected to anther culture to accelerate the production of stable lines, according to PhilRice. BC4F2 and stable anther culture-derived plants will be generated during the first quarter of 2008, for subsequent field-testing during the remainder of the year.

A summary of the approved field-tests since 2004 follows:

| <b>Table 1. APPROVAL REGISTRY FOR FIELD-TESTING of REGULATED ARTICLES<br/>as of July 9, 2007</b>                                                                                                                                                                     |                             |                      |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|----------------------|
| <b>Proposal</b>                                                                                                                                                                                                                                                      | <b>Technology Developer</b> | <b>Date Approved</b> |
| 1. Demonstration of Weed Control Performance of Roundup Ready Corn (RRC) System (DK818 NK603) vis-à-vis Farmers' Practices                                                                                                                                           | Monsanto                    | 11/26/04             |
| 2. Performance of Roundup Herbicide (360 g ae/L IPA Salt (Against Weeds in Glyphosate-Tolerant Corn                                                                                                                                                                  | Monsanto                    | 11/26/04             |
| 3. Field Verification of the Agronomic Performance of the Transgenic Corn Hybrid Stacked (NK603/MON 810) Expressing the Bacillus Thuringiensis Cry1AB Protein for Resistance Against the Asiatic Corn Borer and CP4 EPSPS for Tolerance Gainst the Herbicide Roundup | Monsanto                    | 12/10/04             |
| 4. Performance of Heculex 1 Bt Transgenic Corn Hybrids against Asiatic Corn Borer under field conditions in the Philippines.                                                                                                                                         | Dow Sciences                | 05/02/06             |
| 5. Field Testing of Transgenic Papaya w/ delayed Ripening Trait                                                                                                                                                                                                      | IPB-UPLB                    | 03/20/07             |

Source: Bureau of Plant Industry

A comprehensive plan representing the country's national biotechnology roadmap is contained in the DA's proposed National Biotechnology Program for the 2006-2016 period, an electronic copy of which has been provided the FAS Biotechnology Group. The proposal identifies the needs, the proposed strategies and the corresponding priority program areas it needs to address to move Philippine agriculture forward using traditional and modern agricultural biotechnology. The biotechnology proposal acknowledges that progress in the

commercialization process has been slow and attributes this to the scarcity of well-trained scientists, constrictive accounting and auditing systems (of government), inadequate infrastructure for R & D and unreliable and insufficient funding. In general terms, the roadmap, has for its 3 strategies the following: (1) targeting the world market for natural ingredients; (2) improving the competitiveness of traditional agri-fisheries products; and (3) the establishment of a biotechnology fund.

The Philippines became a net food-importer in the mid-1990's and food imports, since then, have become an essential component of the country's food supply. In terms of value, agricultural imports account for roughly 8 percent of the country's overall merchandise imports. Since 2004, agricultural imports have been growing close to 9 percent resulting in an increasing agricultural trade deficit (refer to Table 2).

| <b>FOB and CIF Value in M\$</b> |             |             |             |                    |                  |
|---------------------------------|-------------|-------------|-------------|--------------------|------------------|
| <b>Item</b>                     | <b>2006</b> | <b>2005</b> | <b>2004</b> | <b>Growth Rate</b> |                  |
|                                 |             |             |             | <b>2006/2005</b>   | <b>2005/2004</b> |
| <b>A. Exports (FOB Value)</b>   |             |             |             |                    |                  |
| Total Exports                   | 47,036.54   | 41,254.68   | 39,680.52   | 14.02              | 3.97             |
| TOTAL VALUE OF AG. EXPORTS      | 2,780.69    | 2,691.19    | 2,510.88    | 3.33               | 7.18             |
| % Ag. Exports to Total Exports  | 5.91        | 6.52        | 6.33        | -9.38              | 3.09             |
| <b>B. Imports (CIF Value)</b>   |             |             |             |                    |                  |
| Total Imports                   | 53,717.57   | 49,487.42   | 46,102.14   | 8.55               | 7.34             |
| TOTAL VALUE OF AG. IMPORTS      | 4,315.32    | 3,975.62    | 3,651.35    | 8.54               | 8.88             |
| % Ag. Imports to Total Imports  | 8.03        | 8.03        | 7.92        | 0.00               | 1.43             |
| <b>C. Balance of Trade</b>      |             |             |             |                    |                  |
|                                 | -1,534.63   | -1,284.43   | -1,140.47   | 19.48              | 12.62            |

Source: Bureau of Agricultural Statistics

In 2006, the Philippines was the 15<sup>th</sup> largest export market for US agricultural, fishery and forestry products, with overall export value increasing by 16 percent reaching \$924 million last year, up from the \$826 million in 2005. Last year, the Philippines was our 3<sup>rd</sup> largest soybean meal market, 5<sup>th</sup> for dairy products, 6<sup>th</sup> for snack foods excluding nuts, 4<sup>th</sup> for wheat, 12<sup>th</sup> for pet food, and 15<sup>th</sup> for consumer-oriented agricultural products. Imports of biotechnology crops and their derivative products are roughly estimated at \$400 million annually. So far, there are no known Philippine exports of GE food products to the U.S. or elsewhere.

The Philippines was a recipient of a FY06 PL 480 Title I allocation (\$20 million worth of rice) and during the same period, was also a beneficiary of a couple of Food for Progress allocations. These included a \$3 million (11,600 MT of soybean meal) and \$4 million grants (11,900 MT of soybean meal plus 6,000 MT of feed peas). Commodities of both programs arrived in 2006.

### **III. Biotechnology Policy**

The responsible GRP regulatory agencies and their roles in relation to Philippine biotechnology regulations remain unchanged from GAIN 5027 and continue to be guided by the DA-AO 8. Under this regulatory regime, 25 TEs of biotech crops for commercial use have been approved for food, feed or processing materials (see Appendix A), higher than the 23 approved TEs reported in the previous annual report. The number of TEs approved for

commercial production remains unchanged from the previous annual report's level at 3, namely: Monsanto's Corn MON810, Corn NK 603, and Syngenta's Corn Bt 11. In addition to the 3 approved TEs, one stacked or combined trait corn variety (Round up Ready corn) composes the 4 biotech crop varieties approved for propagation. There are no fees collected by the BPI once a TE is approved for propagation, but there is a fee when applying. Once a TE is approved, the GE crop is considered as safe as its conventional counterpart and, therefore, no policies on their coexistence in the field apply. One thing monitored by the BPI is the insect management resistance strategy of the GE crop being cultivated.

Currently, the BPI has also approved 15 stacked trait products (Table 3), up from the reported 10 approved combined trait products in the previous annual report.

| Combined Trait Product                          | Technology Developer | Date Approved        | Safety Assessment |      |              |
|-------------------------------------------------|----------------------|----------------------|-------------------|------|--------------|
|                                                 |                      |                      | Food              | Feed | Propa-gation |
| 1. Corn MON810 x Corn NK603                     | Monsanto             | 11/16/04<br>07/19/05 | x                 | x    | x            |
| 2. Corn NK603 x Corn MON863                     | Monsanto             | 11/16/04             | x                 | x    |              |
| 3. Corn MON810 x Corn MON863                    | Monsanto             | 11/16/04             | x                 | x    |              |
| 4. Corn MON810 x GA21                           | Monsanto             | 11/16/04             | x                 | x    |              |
| 5. Cotton 531 x Cotton 1445                     | Monsanto             | 11/22/04             | x                 | x    |              |
| 6. Cotton 15985 x Cotton 1445                   | Monsanto             | 11/22/04             | x                 | x    |              |
| 7. Corn MON863 x MON810 x<br>Corn NK603         | Monsanto             | 02/07/05             | x                 | x    |              |
| 8. Corn TC 1507 X Corn NK603                    | Pioneer              | 02/17/06             | x                 | x    |              |
| 9. Cotton 15985 x Cotton 88913                  | Monsanto             | 04/20/06             | x                 | x    |              |
| 10. Corn MON 88017 x Corn MON 810               | Monsanto             | 07/03/06             | x                 | x    |              |
| 11. Corn LY038 x Corn MON810                    | Monsanto             | 08/09/06             | x                 | x    |              |
| 12. Corn DAS 59122 x Corn NK603                 | Pioneer              | 12/20/06             | x                 | x    |              |
| 13. Corn Bt 11 x Corn GA21                      | Syngenta             | 01/23/07             | x                 | x    |              |
| 14. Corn TC1507 x Corn DAS 59122                | Pioneer              | 01/23/07             | x                 | x    |              |
| 15. Corn DAS59122 x Corn TC1507 x<br>Corn NK603 | Pioneer              | 02/07/07             | x                 | x    |              |

Source: Bureau of Plant Industry

DA-AO 8 is expected to remain in effect until the Implementing Rules and Regulations (IRRs) of Executive Order No. 514 (EO 514) currently being drafted by an inter-agency Technical Working Group (TWG), are approved and issued. The Executive Director of the Philippine Council for Advanced Science and Technology Research and Development sits as chairperson of the NCBP-TWG, which is composed of the following departments and agencies:

1. Department of Environment and Natural Resources (DENR)
  - Protected Areas and Wildlife Bureau (PAWB)
  - Environmental Management Bureau (EMB)
  - Ecosystems Research and Development Bureau (ERDB)
2. Department of Health (DOH)
  - Bureau of Food and Drug (BFAD)
  - Research Institute for Tropical Medicine (RITM)
3. Department of Interior and Local Government (DILG)

4. Department of Science and Technology (DOST)
5. Department of Foreign Affairs (DFA)
6. Department of Agriculture (DA)

The TWG is currently developing the procedural manual/operational guidelines on how to implement EO 514. According to DOST contacts, this manual will define the scope and delineation of responsibilities of the different departments, as provided for by the respective mandates of the different agencies within the departments. Currently, workshops are being planned to address the details of the procedural manual, which is likely to be finalized in December 2007.

Even before this time, however, adjustments in DA-AO 8 guidelines are expected as a result of the lessons learned during its almost 5-year existence. GRP regulators are aware that permits issued and are nearing maturity or expiration under DA-AO 8, such as the Bt corn permit issued in 2002, are likely to be renewed and in so doing, will require regulatory clarification. The DA has likewise been conducting consultations on the approval process of DA-AO 8 directed at avoiding the probable but unintended use of articles approved for feed but not for food, and vice-versa (refer to GAIN 6043).

Other refinements are driven by recent developments in international rules governing trade of biotechnology and biotechnology-derived products such as discussions on AP by the Codex Alimentarius Commission's Biotechnology Task Force. While the country has established safety assessment processes for importing biotech products, protocols to address AP are absent. Being a net food importer, and considering the growth of global production and trade of GE products, there is a growing GRP consensus to accommodate a certain level of unintentionally introduced recombinant-DNA plant materials (e.g., seeds, grains, or plants) in non-GE crops shipments. This is manifest in the GRP's support of the U.S. position on the inclusion of AP as part of the Codex agenda.

On the area of labeling, although the Health Department's BFAD has made known its support for a voluntary labeling regime, it has yet to release formal labeling guidelines that apply to processed foods derived from the use of modern biotechnology.

#### **IV. Marketing Issues**

As mentioned in GAIN 6026, Post recommends developers to provide early the needed documentation the GRP regulatory agencies require, to avoid unnecessary delays in approvals or clearance of biotechnology or biotechnology-derived products to be marketed in the Philippines. This applies to those TEs that are commercially available in foreign countries, as well those undergoing research.

#### **V. Capacity Building and Outreach**

Post continues to support GRP efforts to commercialize local biotechnology projects particularly in the area of Intellectual Property Rights (IPR). Two participants attended the IPR training module in Michigan State University in July last year 2006, and one participant will be attending the same program this year. The Philippine participation in both years were made possible by the Cochran Fellowship Program.

Currently, Post is also recruiting an expert speaker on IPR as part of its outreach program for this fiscal year. In addition, a speaker on AP is being identified for a series of seminars to enhance the GRP's capacity to craft and issue a policy that would address this timely and appropriate topic. Specific training needs and possible capacity building programs may be directed at specific activities contained in the DA's National Biotechnology program.

## APPENDIX A

| APPROVAL REGISTRY FOR THE IMPORTATION OF REGULATED ARTICLES FOR DIRECT USE FOR FOOD, FEED & FOR PROPAGATION |                                                                                                                                         |                      |                   |      |             |           |
|-------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|----------------------|-------------------|------|-------------|-----------|
| as of 7/9/2007                                                                                              |                                                                                                                                         |                      |                   |      |             |           |
| Event                                                                                                       | Introduced trait and gene                                                                                                               | Date Approved        | Safety Assessment |      |             | Developer |
|                                                                                                             |                                                                                                                                         |                      | Food              | Feed | Propagation |           |
| 1. Corn MON 810                                                                                             | Resistance to corn borer Cry 1A (b) gene from Bacillus Thuringiensis                                                                    | 12/04/02             | x                 | x    | x           | Monsanto  |
| 2. Corn Bt 11                                                                                               | Insect protected, herbicide tolerant maize - Bt protein from Bacillus Thuringiensis and PAT protein from Streptomyces viridochromegenes | 07/22/03<br>04/14/05 | x                 | x    | x           | Syngenta  |
| 3. Soybean 40-3-2                                                                                           | Resistance to herbicide, R+B19oundup - CP4 EPSSPS from Agrobacterium sp. Strain CP4                                                     | 07/22/03             | x                 | x    |             | Monsanto  |
| 4. Corn NK 603                                                                                              | Glyphosate tolerance imparted by the CP4EPSPS coding sequence                                                                           | 09/10/03<br>02/08/05 | x                 | x    | x           | Monsanto  |
| 5. Corn MON 863                                                                                             | Cry3Bb1 for resistance to the Corn root worm, Diabrotica sp.                                                                            | 10/07/03             | x                 | x    |             | Monsanto  |
| 6. Corn TC 1507/<br>CRY 1F                                                                                  | Resistance to certain lepidopterous pests in maize - Cry1F and PAT genes                                                                | 10/07/03             | x                 | x    |             | Pioneer   |
| 7. Corn DBT 418                                                                                             | Lepidopteran resistance, phosphino- tricin tolerance - Cry1Ac                                                                           | 10/22/03             | x                 | x    |             | Monsanto  |
| 8. RR Canola                                                                                                | Glyphosate (Roundup) tolerance - CP4EPSPS                                                                                               | 10/22/03             | x                 | x    |             | Monsanto  |

|                                                   |                                                                                                                              |          |   |   |  |                    |
|---------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|----------|---|---|--|--------------------|
| 9. Corn BT 176                                    | Insect protected - Bt protein from Bacillus Thuringiensis and PAT protein from Streptomyces viridochromegenes                | 10/24/03 | x | x |  | Syngenta           |
| 10. Corn GA 21                                    | Modified EPSPS for tolerance to glyphosate                                                                                   | 11/20/03 | x | x |  | Monsanto           |
| 11. Corn DLL25                                    | Phosphinonoin (PPT) herbicide tolerance specifically glutosinate ammonium                                                    | 11/20/03 | x | x |  | Monsanto           |
| 12. Corn T25                                      | Phosphinonoin (PPT) herbicide tolerance specifically glutosinate                                                             | 12/05/03 | x | x |  | Bayer Crop Science |
| 13. Cotton 1445                                   | Tolerance to Roundup herbicide                                                                                               | 12/05/03 | x | x |  | Monsanto           |
| 14. Cotton 15985                                  | Resistance to lepidopterous pests                                                                                            | 12/05/03 | x | x |  | Monsanto           |
| 15. Potato Bt (RBBT02-06) and SPBT02-05           | Resistance to Colorado potato beetle                                                                                         | 12/05/03 | x | x |  | Monsanto           |
| 16. Potato RBMT 15-101, SEMT 15-02 and SEMT 15-15 | Resistance to Colorado potato beetle; resistance to potato virus Y (PVY)                                                     | 12/22/03 | x | x |  | Monsanto           |
| 17. Cotton 531                                    | Resistance to lepidopterous pests Cry 1Ac                                                                                    | 02/05/04 | x | x |  | Monsanto           |
| 18. Potato RBMT21-129, RBMT21-350 and RBMT 22-82  | Resistance to Colorado potato beetle - CryIIIA coding sequence, Resistance to potato leaf roll virus (PLRV) - PLRV replicase | 09/24/04 | x | x |  | Monsanto           |

|                           |                                                                                                                                                                                                                                                                                 |          |   |   |  |          |
|---------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|---|---|--|----------|
| 19. Sugar beet Event 77   | Glyphosate (Round-up) Tolerance                                                                                                                                                                                                                                                 | 10/21/04 | x | x |  | Monsanto |
|                           |                                                                                                                                                                                                                                                                                 |          |   |   |  |          |
| 20. Sugarbeet H7-1        | CP4EPSPS coding sequence from Agrobacterium spp. CP4 strain                                                                                                                                                                                                                     | 07/28/05 | x | x |  | Monsanto |
|                           |                                                                                                                                                                                                                                                                                 |          |   |   |  |          |
| 21. Cotton MON 88913      | Cotton contains the cp4 epsps coding sequence from soil bacterium, Agrobacterium sp. Strain CP4 which confers resistance to glyphosate, the active ingredient in Round Up herbicide                                                                                             | 11/29/05 | x | x |  | Monsanto |
|                           |                                                                                                                                                                                                                                                                                 |          |   |   |  |          |
| 22. Corn MON 88017        | Contains Cry3Bb1 for resistance to the corn rootworm, Diabrotica spp and cp4 epsps for tolerance to glyphosate herbicide                                                                                                                                                        | 03/08/06 | x | x |  | Monsanto |
|                           |                                                                                                                                                                                                                                                                                 |          |   |   |  |          |
| 23. Corn LY038            | Contains cordapA coding sequence which is under control of the maize Glb1 promoter tha expresses the Corynebacterium glutamicum derived lysine insensitive dihydropicolinate synthase enzyme in the germ to increase the level of lysine in grain for animal feed applications. | 05/19/06 | x | x |  | Monsanto |
|                           |                                                                                                                                                                                                                                                                                 |          |   |   |  |          |
| 24. Alfalfa J101 and J163 |                                                                                                                                                                                                                                                                                 | 08/09/06 | x | x |  | Monsanto |
|                           |                                                                                                                                                                                                                                                                                 |          |   |   |  |          |
| 25. Corn DAS 59122-7      |                                                                                                                                                                                                                                                                                 | 08/09/06 | x | x |  | Pioneer  |

Source: Bureau of Plant Industry