Philippine American Academy of Science and Engineering (PAASE)

A Statement of Support for the Resumption of Research and Development and Field Testing of Bt Eggplant in the Philippines Under the New DOST-DA-DENR-DOH-DILG Joint Department Circular No. 1, Series of 2016

The Philippine American Academy of Science and Engineering (PAASE)[1] expresses its strong support for the prompt resumption and continuation of research and development and field testing of Bt eggplant (or *Bt talong*) in the Philippines under the newly enacted DOST[2]-DA[2]-DENR[2]-DOH[2]-DILG[2] Joint Department Circular No. 1, Series of 2016, titled *Rules and Regulations for the Research and Development, Handling and Use, Transboundary Movement, Release into the Environment, and Management of Genetically-Modified Plant and Plant Products Derived from the Use of Modern Biotechnology*.

Eggplant, the leading vegetable crop in the country in terms of both volume and area of production, is a valuable source of income for Filipino farmers. Eggplant production in the Philippines covers approximately 22,000 hectares, yielding a volume of about 220,000 metric tons annually, valued at about PhP 2.6 B.

Economics and Food Security

The emergence of the fruit and shoot borer (FSB) as a major pest of eggplant in the country has been catastrophic to both farm productivity and farmers' income, and has imperiled food security in vast areas heavily invested in the crop. Indeed, an estimated 51 to 73 percent of the crop is lost when no form of pest control is provided. Such potential massive production losses prompt the liberal application of 60 to 80 pesticide sprays during a planting season, costing farmers about PhP 28,000 per hectare on pesticides, representing 29 percent of total production costs. Consequently, eggplant products become not only laced with pesticides, but their price also jumps from ordinarily about PhP 45 per kilo to PhP 70 per kilo – an unaffordable price to most urban low-income consumers.

Given the lack of effective pest-control approaches against FSB available to Filipino eggplant farmers, the development of an alternative technology in the form of *Bt talong* -- devoid of the established risks to humans, farm animals and other non-target organisms that chemical

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[1]The Philippine American Academy of Science & Engineering (PAASE) is an international organization of scientists and engineers who have distinguished themselves in scholarly and research-related activities and who are of Philippine descent -- based in the Philippines, the United States or elsewhere. PAASE promotes the advancement of science, engineering and technology; encourages collaborative efforts among scientists and engineers; and supports national inclusive growth and development through innovation in science and technology. PAASE was founded and incorporated in the State of Indiana on April 23, 1980.

[2]DOST, Department of Science and Technology; DA, Department of Agriculture; DENR, Department of Environment and Natural Resources; DOH, Department of Health; DILG, Department of Interior and Local Government.

pesticides typically pose -- becomes both a desirable and an urgent imperative. Growing *Bt talong* is expected to significantly increase agricultural productivity in areas severely affected by FSB, and is projected to raise farmers' income by about P50,000 per hectare. Indeed, the development of *Bt talong* cultivars directly supports the country's aspiration for inclusive growth and poverty reduction.

Human and Animal Safety

Results from numerous biosafety and toxicological studies have allowed the U.S. Environmental Protection Agency (EPA) and the World Health Organization (WHO) to conclude that the consumption of genetically modified (GM) farm products which produce Bt toxins is safe and unlikely to pose health hazards to humans and non-target animals owing to the specificity of the insecticidal activity of Bt toxin to specific arthropods.

According to an offical 2010 European Union (EU) report, “there is, as of today, no scientific evidence associating [genetically modifed organisms] GMOs with higher risks for the environment or for food and feed safety than conventional plants and organisms". Likewise, 22 major scientific bodies have vouched for the safety of GM food and crops in use today.

In Asia, Bangladesh has already approved the commercial planting of *Bt talong*, and its government has been providing seeds to farmers on a royalty-free basis since 2013. In India, *Bt talong* is awaiting commercial approval after receiving a positive biosafety determination. Meanwhile, the Philippines was the first country in Asia to approve the commercial cultivation of GMO corn for food and animal feed in 2002. Today around 70 percent of the corn planted in the Philippines is GMO. The Philippines has also been importing GMO crops, particularly soybeans and cotton, for more than a decade.

Environmental Safety

In the United States, where over 80 percent of corn, cotton and potato crops grown are Bt transgenic cultivars, the assessment of their ecological impact has been generally benign because of the high insect-target specificity by Cry toxins. Indeed, the pattern that has emerged from many laboratory and field biosafety studies designed to investigate the effects of Bt crops on the food web, and also on harmless and beneficial non-targets, is that Bt crops show minimal, if any, negative impact on harmless or beneficial insects.

Nonetheless, of the various facets of Bt crops -- including agricultural productivity, human safety, food-security impact, intellectual property rights, etc. -- environmental safety frequently elicits the most concerns and sharp contentions from among opponents of Bt crops. The alarms and concerns stem largely from what remains to be a relatively limited amount of empirical data available to make final and unequivocal conclusions on the environmental biosafety of Bt crops across all known agroecologies.

Given, however, that extensive research studies have provided scientific evidence for the relative safety of Bt-derived insecticidal proteins in humans and animals -- and considering the projected significant positive impact of Bt talong on the Philippines' food security and farmers' incomes -- the resumption and continuation of the research and development and field-testing of *Bt talong* in the Philippines with a view to generating the necessary empirical data to evaluate its environmental biosafety specifically in the Philippines is fully justified and should be urgently prioritized.

Intellectual Property

Analysis of the relevant technology-transfer arrangements, the patent and plant-variety protection on *Bt talong* reveals that Filipino farmers would be able to grow *Bt talong* cultivars without royalty costs and, thus, would not become economically subservient to any particular entity that would otherwise be able to control the *Bt talong* market. From an intellectual-property standpoint, Filipino farmers are well-positioned to reap the economic benefits of cultivating the insect-resistant Bt talong cultivars.

Conclusion

We urge all parties involved to take prompt and responsible actions, under Joint Department Circular No. 1 Series of 2016, to implement the resumption and continuation of research and development and field testing of *Bt talong* in the Philippines. As the Philippine American Academy of Science and Engineering (PAASE), we commit to working with the Philippine government, universities and the public, if called for, in providing expert advice and recommendations on the various facets of the development and use of *Bt talong* in the Philippines.

We call on Philippine government leaders, farmers, academics, scientists, engineers, the private sector, journalists, students and the general public to:

- Acknowledge that the development and field testing of *Bt talong* is an urgent imperative to provide an effective, safe and sustainable solution to the economically and environmentally ruinous problem currently facing Filipino eggplant farmers;

- Mobilize the Filipino science and technology community to launch a nationwide educational and extension program to disseminate accurate scientific facts and information on *Bt talong* and to combat any misinformation and disinformation on the subject; and,

- Work with Filipino eggplant farmers to build scientific and technological capacity best suited to their circumstances in regard to sustainable and cost-effective integrated cultivation management practices.

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The Impact of Bt Talong on Agricultural Productivity and Food Security

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Agricultural productivity and food security are intimately entwined terms. The former influences the latter in a deterministic manner. When agricultural productivity is high, food security is ensured.

Eggplant is the leading vegetable crop in the country in terms of volume and area of production, which covers about 22,000 hectares. It figures significantly in the daily food requirements of the average Filipino family. It is a valuable source of income for farmers especially those close to Manila and other big cities. Before the invasion of the fruit and shoot borer (FSB), truckloads of eggplant were transported from Pangasinan to Manila on a daily basis.

The emergence of the FSB as a major pest of eggplant was precipitated by a disregard of the basics of ecological diversity and balance. At the outset, when this pest was of negligible importance it was ignored as the continuing cultivation of the crop, demanded by a growing market, afforded steady income. In many eggplant-growing areas, ratooning of the crop, which provided almost uninterrupted host presence, exacerbated localized outbreaks. These outbreaks predictably coalesced into epidemics as wider and contiguous areas were planted in order to satisfy the market. In the process, the dynamics of the pest as it slowly multiplied seemed to have been ignored.

The outcome is a disaster both for farm productivity and farmers' income. It imperils food security in areas heavily invested in the crop. By current account, 51-73% of the crop is lost when any form of control is not provided. This magnitude of loss has prompted the use of 60 to 80 pesticide sprays during the planting season. In extreme cases, unharvested eggplant fruits are dipped into a mixture of several chemicals to ensure higher yield. Other control approaches, such as manual removal of infested shoots, crop rotation, intercropping, using nylon net barriers, trapping of the male using pheromones, applied either singly or in an integrated manner, are typically labor-intensive and generally ineffective. The development, therefore, of an alternative technology in the form of a Bt *talong*, devoid of risks to humans, farm animals and other non-target organisms inherent in the use of chemicals, is a preferred solution.

Bt *talong,* developed through biotechnology, unburdened by the problems of conventional breeding, harbors a natural protein governing host resistance and is specific to the FSB. Growing Bt *talong* is projected to reduce losses significantly and increase agricultural productivity in hard-hit areas. Average potential incomes of P124,000-P130,000 (Quicoy, 2014) and P133,000 - P272,000/ha (Francisco, 2014) for eggplant farmers are expected.

The continuing use of Bt *talong* should provide a steady supply of a sufficient quantity of affordable and nutritious food for optimal nutrition. It makes available a healthy and safe source of food bereft of the lingering fear of insecticide poisoning. The attainment, therefore, of food security, perceived to exist when all people at all times have physical and economic access to adequate amounts of nutritious, safe, and culturally-appropriate food to maintain a healthy and active life, becomes closer to reality.

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Economic Advantages of the *Bt-Talong* Technology

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Agriculture in perspective

Agriculture accounts for only about a tenth of the Philippines' gross domestic product (GDP) while it employs close to 30 percent (11.5 million) of the total employed labor force (Philippine Statistics Authority [PSA 2015]). This readily explains why the majority (ca. 70% or 19 million in 2015) of the country's poor are in rural areas, mostly small farmers and fishers. Poverty incidence is 40 percent in rural areas versus 13 percent in urban areas.

Agriculture has generally been characterized as small-hold subsistence farming of mostly traditional crops resulting in low income (Quicoy 2014). Farmers have typically been producing for home consumption, then selling any marketable surplus. They have not been accustomed to doing farming as a business enterprise. Obviously, such farming practice cannot be sustained in the era of globalization or just even in the context of ASEAN integration.

Vegetable farming is considered among the most important sub-sectors in agriculture. This is indicated not only in terms of total area planted to vegetables (211,789 hectares in 2014 [PSA website]) but also as a major source of income to millions of rural folks in the country. Moreover, it contributes millions of dollars (US$2,315,649,404 in 2014 [PSA website]) to the country's foreign exchange earnings. As well, vegetable production has forward linkages to other enterprises, such as food processing and restaurants. Further, vegetables provide the cheapest source of protein, minerals and vitamins needed for proper nutrition and, hence, are critical to the country's food security.

Despite the importance of the vegetable sub-sector in the Philippine economy, the production and area harvested has declined by 4.4 percent (or 0.16% annually [PSA website]) since 1990, implying neglect on the part of the government. In recent years, the condition – including the poverty situation in vegetable-based communities – caught the attention of the government. This has led to the implementation of programs and projects (e.g., R&D on eggplant) aimed at increasing vegetable productivity and incomes, involving new technologies for vegetable farming and identifying new areas suited for vegetable production (Quicoy 2014). Given the relatively poor performance of the major traditional crops (e.g., grains, sugar, and coconut), support to alternative crops – small eggplant farming among them – has become among the priority concerns of the Aquino Administration. Partly because of government support, Bt Talong had been in the final phase of field testing preparatory to commercialization when the Philippine Supreme Court (SC) handed down its decision on 8 December 2015 to stop further field tests.

Bt Talong

The recent enactment of the DOST-DA-DENR-DOH-DILG Joint Department Circular No. 1, Series of 2016, titled *Rules and Regulations for the Research and Development, Handling and Use, Transboundary Movement, Release into the Environment, and Management of Genetically-Modified Plant* – superseding the Department of Agriculture Administrative Order No. 8, series of 2002, which had been struck down by the Philippine Supreme Court – paves the way for the continuation of progress in the country's science and technology (S&T), particularly in agriculture, but also to its aspiration for inclusive growth and poverty reduction (Pernia 2016).

Development of the *Bt talong* and other GM products in general was spurred by the need for food security for all, particularly the poor in rural areas (Rola 2016). It aimed to provide consumers easy access to safe foods produced without harm to farmer's health and the environment (Francisco 2014a). Moreover, *Bt talong* technology brings about higher profits to farmers owing to lower production costs which, in turn, are passed on as lower-priced eggplants to consumers, especially given an efficient marketing system.

By contrast, the pesticide technique adversely affects farmers' incomes, as shown by a study of 100 eggplant farmers in four provinces where crop damage caused by the fruit and shoot borer (FSB) had become increasingly severe over time (Francisco 2014b, as cited in Rola [2016]). The average yield of the farmer-respondents was lower at 21.56 metric tons in the last year of the project compared with the 25.35 metric tons average yield over the five-year duration of the project. Farmers spent about P28,000 per hectare on pesticides to counter FSB, representing 29 percent of total production costs. Eggplant products were not only laced with pesticides, they also cost about P70 per kilo (versus P45 per kilo of organically grown eggplant based on key information in Los Banos retail markets) – an unaffordable price to urban low-income consumers. By contrast, *Bt talong* with lower insecticide residue would be cheaper to consumers, encouraging thereby wider consumption of this more healthful food.

According to Francisco's earlier economic impact study (2007), *Bt talong* cultivation could raise farmers' incomes by about P50,000 per hectare owing to higher yield and production cost savings of 16 percent attributable to controlling FSB per se, while eggplant farmers typically also spray pesticide on other kinds of pests and diseases including weeds. The marked increase in farmers' incomes is consistent with further research showing that adoption of *Bt* eggplant technology has appreciable potential to reduce poverty incidence in farming communities, besides improving the nutrition of eggplant consumers in general (Francisco, Aragon-Chiang and Norton 2014, as cited in Rola [2016]).

The Bigger Picture

Bt technology actually covers a wide variety of products – *Bt talong* being just a relatively small part – such as *Bt* corn and *Bt* soybean used as feeds for the poultry and livestock industries, as well as meat products and food products using meat, corn and soybean oil. According to Philippines Bureau of Agriculture Statistics (BAS) data (as cited in Dy [2016], about 95 percent of yellow corn produced by small farmers was *Bt,* harvested from nearly one million hectares producing five million tons, representing some 70 percent of all corn production in the Philippines. The farmers numbered 500,000, with their farm output valued at close to P50 billion (Dy 2016). "The fertilizer and seed component of this output will be over P10 billion a year. Some sectors would say that they can be replaced by open-pollinated corn, but the farm income would be much lower, and so would be the production," says Dy (2016).

The decision by the Philippine Supreme Court to temporarily enjoin the importation of genetically modified organisms (GMO) – which remained in effect until the recent promulgation of the Joint Department Circular No. 1, Series of 2016 – understandably caused significant concerns across the country's agricultural sector and beyond.

"The impact on the hogs, chicken broiler and layer industries would be tremendous. Imports of non-Bt corn and soybean are not sound options as supply is very limited and at very high cost. Aquaculture, mainly bangus and tilapia, will also be impacted as fish feeds contain soybean meal. About 20 percent of fish feed uses soybean meal. Non-GM soybean meal costs 40 percent higher" (Dy 2016).

Because the animals could not mature to their desired size and weight owing to scarce and costly feeds, meat prices would have to rise for raisers to continue producing underweight animals. Parenthetically, organic pigs and chickens would have been doubly pricey. Supply of meat and eggs would have been limited as most of the corn would come from *Bt* sources, imports mainly from the U.S. and Argentina (Dy 2016). Household budgets would have been hit as home-cooked food would become considerably costlier, and as meat and eating-out expenditures typically account for close to 20 percent of total family expenditures (Family Income and Expenditure Survey 2012). Then, too, collateral damage would have befallen the restaurant and hotel businesses and, by extension, the country's tourism industry.

The Philippines in 2015 imported some 2.35 million tons of *Bt* soybean meal (the main source of protein [energy from *Bt* corn] in animal feeds) mostly from the U.S. This enabled the country to produce 2.12 million tons of pigs, 1.66 million tons of chickens, and 445,000 tons of eggs. The total value of farm output was nearly P400 billion (BAS 2015). Another 210,000 tons apiece of pork and chicken meat were imported, mostly fed with Bt corn and Bt soybean, accounting for around 13 percent and 19 percent, respectively, of domestic consumption in the Philippines (USDA). Meanwhile, in 2014, the country produced 390,000 tons of bangus and 259,000 tons of tilapia (BAS 2015).

The implied potential job losses stemming from the value chain and other ramifications would have also been staggering. As well as in agriculture, employment in the service sector and industry (e.g., food processing, restaurants, tourism) would have been impacted.

Given the projected dire consequences of the decision by the Philippine Supreme Court to temporarily enjoin the importation of GMOs, the recent enactment of the DOST-DA-DENR-DOH-DILG Joint Department Circular No. 1, Series of 2016 is welcome indeed, and serves to avert the projected dismal scenario for the country's agriculture and economy.

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***Bt Talong* and Human Safety**

Lourdes J. Cruz, Ph.D. and Alice Tarun, Ph.D.

Bacillus thuringiensis (Bt) is a soil-dwelling bacterium that has been used to control insect pests since the 1920s. Its spores and crystalline insecticidal proteins are used in formulations marketed as organic pesticides under trade names such as DiPel, Thuricide, Costar, Bio-Trol and BioProtec to kill mosquito larvae and to control caterpillars of moths and butterflies, which destroy many crops and ornamental plants. Bt spray has been used for over 50 years and organic farmers consider Bt innocuous. It occurs naturally in the gut of some caterpillars, on leaf surfaces and in aquatic environments and it has been found also in animal feces, insect-rich environments, flour mills and grain-storage facilities.

The δ-endotoxins including Cry1Ac are toxic proteins produced by *B. thuringiensis.* They are actually pro-toxins that get dissolved and activated in the alkaline midgut of susceptible insects, where the activated toxins bind to specific receptors, destroy the integrity of membranes and ultimately kill the insect. The endotoxins do not affect humans because humans like other mammals do not have receptors for Bt toxins. Moreover as proteins, Bt toxins are digested and rendered inactive by enzymes in the acidic environment of the stomach then by other enzymes in the alkaline environment of the intestines.

Numerous safety studies have been conducted on Bt spray formulations and Bt toxins produced in genetically modified organisms (GMOs) showing that Bt toxin is nontoxic to humans and non-target animals. Animal toxicology studies confirmed these results since test animals fed with high concentrations of Bt formulations from GMOs, or even the GMO crops themselves, exhibited no adverse reactions nor showed abnormalities in their gut when examined under the microscope. The results from these studies have enabled the U.S. Environmental Protection Agency and the World Health Organization to conclude that consumption of GMOs which produce Bt toxins is safe and unlikely to pose a health hazard to humans and non-target animals owing to the specificity of the insecticidal activity of Bt toxin to specific arthropods.

The gene for Cry1Ac has previously been used to confer insect resistance to commercially important crops such as cotton and tomatoes. Similarly, the resistance of Bt talong to fruit and stem borer (FSB) caterpillars, which can reduce yileds by 50 percent, is due to the presence of the gene for Cry1Ac. The gene has been introduced into local eggplant varieties by crossing with a highly insect resistant Bt eggplant developed in India. The researchers at UP Los Baños initiated studies on Bt talong because of their great concern for the safety of farmhands who are highly exposed to toxic chemicals due to repeated treatments of talong with insecticides. With the projected availability of a FSB-resistant Bt talong, the danger from insecticides could be avoided. Field trials testing the safety and FSB resistance of Bt talong were conducted in the Philippines, India, and Bangladesh. In India, Bt talong is awaiting commercial approval after receiving a positive safety determination. While Bangladesh has approved the commercial planting of Bt talong and has provided seeds to farmers on a royalty-free basis since 2013.

GM crops are considered safe because production of GM crops and foods are highly regulated locally and internationally at every stage of research and development from the laboratory to field testing and commercialization. The Philippines was the first in Asia to approve commercial cultivation of a GMO corn for food and animal feed in 2002. Around 70 percent of the corn planted in the Philippines is GMO. The Philippines has also allowed GM crop imports particularly GMO soybean and cotton for more than a decade.

Close to 2,000 peer-reviewed publications in the scientific literature document the safety of GM foods, contrary to the claim of anti-GMO groups that governments have relied on the safety of GMOs just on claims of commercial producers of GM food. Among the concerns raised by an anti-GMO advocate against GM crops is the perceived link with allergens, which was based on the misinterpretation of the results of a publication where a Bt endotoxin was used in relatively high amounts as an adjuvant for the production of antibodies.

According to the EU 2010 report on EU-funded projects, “there is, as of today, no scientific evidence associating GMOs with higher risks for the environment or for food and feed safety than conventional plants and organisms". Likewise, 22 major scientific bodies have vouched for the safety of GM food and crops in use today including:

- World Health Organization (WHO)
- International Council for Science (ICSU)
- American Association for the Advancement of Science (AAAS)
- US National Academy of Science (US NAS)
- American Medical Association (AMA)
- European Commission (EC)
- The Royal Society of Medicine (RSM)
- The Royal Society of London (RSL)
- Federation of Animal Science Societies (FASS)
- Union of German Academies of Sciences and Humanities (UDAW)
- French Academy of Science (FAS)
- International Society of African Scientists (ISAS)
- International Seed Foundation (ISF)
- Council for Agricultural Science and Technology (CAST)
- American Council on Science and Health (ACSH)
- American Dietetic Association (ADA)
- American Society for Cell Biology (ASCB)
- American Society for Microbiology (ASM)
- American Society of Plant Sciences (ASPS)
- Society for In Vitro Biology (SIVB)
- Society of Toxicology (ST)
- Consensus Statement on GMOs representing 14 Italian scientific organizations.

The above are well respected bodies of scientists who uphold the integrity and objectivity of science. In particular, the mission of ICSU is “to strengthen international science for the benefit of society” and its vision is “a world where science is used for the benefit of all”.

GMOs developed by Filipino scientists can greatly help the country particularly the poor communities as the Philippines tries to achieve food security.

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Bt Eggplant: Current Assessment on Environmental BioSafety

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Since 1995, a wide range of transgenic crops including corn, cotton, potato, rice, tomato, broccoli and most recently eggplant (also called Bt Talong) have successfully used the systemic expression of insecticidal proteins, including the Cry 1Ac δ-endotoxin from the soil bacterium *Bacillus thuringiensis Berliner* (Bt), to selectively control lepidopteran pests.

Of the various facets of Bt crops -- including agricultural productivity, human safety, food-security impact, intellectual property rights, etc. -- environmental safety frequently elicits the most concerns and sharp contentions from among opponents of Bt crops. The alarms and concerns stem largely from what remains to be a relatively limited amount of empirical data available to make final and unequivocal conclusions on the environmental biosafety of Bt crops across all known agro-ecologies. It does not help that most of the empirical studies on Bt crops have been conducted in developed countries. In developing countries, including Asia, the scientific data on the biosafety of Bt crops based on field tests remain limited.

Given, however, that extensive research studies have provided scientific evidence for the relative safety of Bt-derived insecticidal proteins in humans and animals -- and considering the projected significant positive impact of Bt talong on the Philippines' food security and farmers' incomes -- the resumption and continuation of the research and development and field-testing of *Bt talong* in the Philippines with a view to generating the necessary empirical data to evaluate its environmental biosafety specifically in the Philippines is fully justified and should be urgently prioritized.

A. Two Categories of Environmental Impact

It is imperative that the field testing of Bt talong in the Philippines address its potential environmental, ecological and evolutionary impact. Following are the two broad categories of principal environmental impact (2, 3, 4) that the field testing of Bt talong should address.

1. Impact on insect-fitness reduction. *What are the impacts of Bt crops on the insect-dependent food web, on pollinating plants, on surrounding community diversity as well as the emergence of resistant pests?*

In the United States, where over 80% of corn, cotton and potato grown as crops are Bt transgenic cultivars, the assessment of their ecological impact has been relatively benign because of the high insect target specificity of killing by Cry toxins (4). It has been demonstrated that these crops are particularly protected against European and American corn borers, bollworms, budworms, and potato beetle among others of similar taxa. Many of the laboratory and field biosafety studies were designed to investigate the effects of the Bt crops on the food web, and also on harmless and beneficial non-targets. The emerging pattern, based on the application of appropriate meta-analysis of qualitative and quantitative data from several selected studies show minimal, if any, negative impact on harmless or beneficial insects.

The following are important avenues for further investigation:

a) Reassesment of whether the tri-trophic scale models used (i.e. plant – insect – predator) and the duration of observations (typically ≥ 3 years) (4 and references therein,5,6) are significantly limited;

b) Evaluation of non-target effects. A prominent case in the literature involved the laboratory-based investigations showing a susceptibility of monarch butterflies to Cry-expressing corn pollen (7). However, large-scale field trials did not show adverse effects. It is worth questioning whether the presence of monarch butterflies did not coincide with corn flowering in the region (8). This case emphasizes the importance of conducting studies in proper agro-ecological contexts;

c) Assessment of effects of Bt crops on biodiversity. Current studies show few or no toxic effects of Bt plants or Cry proteins on the composition and interactions of soil organisms (9). Arguments have been made that Bt crops can contribute to soil ecosystem health because of less herbicide use; empirical data, however, are needed to substantiate the arguments;

d) Evaluation of impact of Cry protein in aquatic ecosystem. A study in the U.S. have looked at the impact of Cry protein in aquatic ecosystem using Bt corn as model, and revealed a potential negative impact on caddisflies population (10). Questions were raised about the methodology of the study, however. A few other studies that have shown minimal effects of Cry protein exposure in aquatic invertebrate populations also have methodological weaknesses (11, 12, 13). The foregoing underscore the complexity of making aquatic risk assessments due to current deficiencies in realistically modeling aquatic exposure to genetically modified plant material. The more rigorous quantitative study designs have just been recently formalized and initially tested (13). Their adoption could help decribe quantitatively the dynamics between Bt crops farming and neighboring aquatic environments.;

e) Evaluation of impact of Cry protein in soil ecosystem. Studies have been conducted revealing the release of Bt protein from the root exudates of Bt corn into the soil rhizosphere [Saxena D, Flores S, Stotzky G. Insecticidal toxin in root exudates from Bt corn. Nature 1999; 402:480.]. Subsequent studies confirmed the presence of Bt proteins in the exudates from Bt corn and verified that these proteins are biologically active based on an insecticidal bioassay [Tapp H, Stotzky G. Insecticidal activity of the toxins from *Bacillus thuringiensis* subspecies kurstaki and tenebrionis adsorbed and bound on pure and soil clays. Appl Environ Microbiol 1995b; 61:1786-90.]. Moreover, particles of rhizosphere soil placed directly on the bioassay medium caused mortality comparable to the supernatants. These results confirmed earlier findings with purified proteins and surface-active particles that the Bt proteins bind rapidly on soil particles and that the bound proteins retain insecticidal activity and are protected by binding against biodegradation. Thus, the environmental fate of the Cry protein from Bt Talong under relevant environmental conditions should be assessed in the Philippines, including the importance of pH, photodegradation, and other physicochemical and biological characteristics of soil on the persistence of Cry proteins in the Philippine soils. Because persistence and toxicity could potentially be maintained when Bt proteins are bound on surface-active particles in the environment (e.g., clays and humic substances), it is important to conduct field studies in different types of soils that are representative of the eggplant producing regions in the Philippines. Knowledge from such investigations is necessary for a successful implementation of integrated pest management plans to minimize potential environmental hazards that can result from improper practices surrounding the use of Bt crops;

f) Assessment of indirect effects of Bt talong. A case of indirect, but unanticipated effect of Bt crop farming was reported recently from China, based on a 10-year study of Bt cotton farming (14, 15). It revealed a strong co-association between an outbreak in local invasiveness of mirid bugs (a non-target local pest) and Bt cotton adoption with subsequent drop of pesticide use. They specifically demonstrated that Bt cotton became a reservoir of mirid bugs, elevating their status as pest to cotton and multiple other crops. This article published in Science underscores three critical lessons: (1) The importance of conducting long-term studies to reveal, not just direct effects, but also indirect and unintended impacts of Bt crop farming on agro-ecology as a result of altered pest management regimes; (2) The risk assessments on the potential negative effects of Bt crops must not neglect the context of current pest management practice for a given crop; and (3) The rigorous local assessment of each individual Bt crop is important since each presents unique evolutionary pressures on the local agro-ecology; and,

g) Assessment of insect resistance. It is important to assess how fast insect resistance can emerge in Bt crop adoptions, and whether it present new challenges. For instance, a recent global survey of five continents consisting of 77 field studies showed a slow but accelerating trend in pest resistance (16). In 2005, only 1 pest species was identified. In 2012, when this survey was completed, 5 of 13 major pests examined showed field-evolved resistance. This study uncovered genetic factors that delayed the inheritance and frequency of resistance alleles. Their findings provided a theoretical framework that can be exploited to predict resistance risks and suggest strategies to maintain pest population susceptibility towards Bt crops within a local agro-ecology.

2. Crop-fitness-enhancing trait of the transgenic plant. *What is the consequence of transgene flow to native, wild relatives?*

The following are important avenues for further investigation:

1) This question is particularly relevant to Bt crops in the grass family such as Bt corn or Bt rice that might have “weed”-like relatives, but the phenomenon with its accompanying ecological impact in theory holds true to all Bt crops. For Bt crops, a major concern is the acquisition by the wild relatives of the insect-resistant trait from the Bt transgene with progressive gene flow through hybridization and introgression. This concern requires empirical verification. Could pollinators (e.g. bees, butterflies), humans and their agricultural practices, or other non-biological factors (e.g. wind) play major roles? Are the dynamics of the potential gene flow crop-specific and/or region-specific?

2) A principal criticism of earlier empirical studies of transgene flow dynamics of Bt crops was that they were too simplistic in their design, focusing on one or a few factors at a time and thus falling short in simulating the complex landscape and ecology of commercial farming. Experimental designs that simultaneously quantifies complex factors are now being employed. For instance, initial studies recently were done using Bt cotton as a model, leading to information-rich data with high predictive value in assessing the impact of pollinators and human activity on pollen and seed-mediated gene flow (17). A key finding that emerged is the surprising lack of contribution of pollinators to gene flow, long assumed to be a major factor in driving the process. The study served as a snapshot of the complex forces that are at play in transgene flow, emphasizing the importance of empirical verification.

B. Effects of Cry proteins versus Conventional Pesticides for Eggplant

One of the most important environmentally-relevant consequences of using Bt crops is the resultant significant reduction in the use of insecticides for crop production. For instance, some studies have found evidence that the use of Bt corn and Bt cotton is associated with a suppression of the overall population of damaging pests, leading to the decreased use of broad-spectrum pesticides. The use of Bt-talong in the Philippines can potentially reduce the widespread use of persistent pesticides such as chlorantraniliprole [tradename:Prevathon], organophosphates [e.g. tradename: malathion, Brodan (chlorpyrifos)], carbamates [tradenames: Lannate, Padan, Triband], and pyrethroids [tradename: Magnum (cypermethrin), which are among the most prevalently used insecticides for eggplant production in the Philippines. Residues of many of these insecticides have been detected in eggplant, soil, and water [Lu, 2011, Water Air Soil Pollut (2011) 220:413–422] in a study conducted in Pangasinan, the largest eggplant producer in the Philippines.

Organophosphates and carbamates can cause a wide range of health effects, from skin itchiness and rashes, to increased risk of non-Hodgkin lymphoma. Similarly, pyrethroid poisoning among farmers is not uncommon, as revealed by symptoms such as abnormal facial sensations, dizziness, headache, fatigue, nausea, loss of appetite, and signs of muscular fasciculation. Clearly, a reduction on the need to apply large amounts of pesticides resulting from the use of Bt talong has wide-ranging positive impacts on both environment and human health, as well as on the economic aspects related to the use of conventional pesticides.

Since the environmental fate and effects of conventional pesticides are well known, their negative impacts on the environment can be minimized when proper caution and pest management implementation are observed. By the same token, it is thus important to assess the environmental fate and potential effects of Cry proteins so that they could be minimized through proper implementation practices and management.

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Intellectual Property Considerations for *Bt Talong*

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A common concern driving the opposition to Bt technology is the perceived cost of the associated intellectual-property rights, with "TNCs [transnational corporations] like Monsanto . . . using the technology not so much to aid food production but to make a profit out of putting already impoverished farmers into further penury."[1] Analysis of the relevant technology transfer arrangements and the patent and plant variety protection landscapes, however, reveals that, at least in the matter of Bt talong, this concern over intellectual-property issues is unfounded.

Importantly, Bt talong was generated under a royalty-free license[2] using the eggplant lines developed by Maharashtra Hybrid Seeds Company (Mahyco), an agricultural company based in India. Bt talong "will be made available on a royalty-free basis to smallholder farmers."[3] All these ensure that Filipino farmers will be able to grow Bt talong without royalty costs, without enslavement to power-wielding technocrats, and without perpetuating the "rich get richer, and the poor get poorer" trajectory.

Moreover, no Philippine patent covers Bt talong. Mahyco has a Philippine patent relating to the Bt-talong technology, Patent No. 1/2008/501818, entitled "Transgenic Brinjal (*Solanum melongena*) comprising EE-1 event." Analysis of the patent, the prior art, and Philippine patent law, however, suggests that this patent does not confer an iron-clad monopoly on, i.e., does not definitively and completely cover, the use of Bt talong varieties that will enable Mahyco to extract outrageous fees from Filipino farmers.

The Mahyco patent does not directly cover propagation of Bt talong varieties by Filipino farmers, in our opinion. Most of the claims of the patent are directed to methods, kits, and DNA fragments for detecting the Bt gene in the plant. These will not be relevant to the Filipino farmer, who will be growing Bt talong without conducting any molecular analysis on the plants. Further, tools for detecting the Bt gene not covered by the patent claims are available.

The only other claim in the Mahyco patent is directed to "a progeny," but because the claim is vague and includes many elements, it is unclear whether it literally covers the Bt-talong plant and fruit. In any event, Philippine patent law excludes plant varieties from patent protection.[3] Accordingly, Bt talong varieties would not be included in this "progeny" claim.

Moreover, Bt talong as described in the Mahyco patent is arguably not worthy of patent protection, at least in the Philippines at the time the Mahyco patent application was filed because of what was already known in the public domain at that time. To be sure, Bt talong development involved a significant investment in time and resources, like any plant breeding program. The Bt technology, however, was already known in the art long before February 9, 2007, the international filing date of the Philippine patent, such that making Bt talong does not

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[1] AGHAM open letter dated January 22, 2016, see http://agham.org/press-releases/scientist-group-warns-railroading-gm-plant-policy-calls-transparency-crafting-law.

[2] See "University of the Philippines Readies Borer-Free Eggplant," Crop Biotech Update, Sept. 3, 2010, available at http://www.isaaa.org/kc/cropbiotechupdate/article/default.asp?ID=6632.

[3] See Section 22.4, Republic Act 8293.

appear to involve an inventive step, a requirement for patentability. For example, Bt crops were first commercialized in 1996;[4] the potential of the Bt technology to dramatically reduce yield losses from insect pests was already recognized in 1994;[5] and insect-resistant transgenic eggplant using Bt technology had already been described in 1997.[6] Given all these pieces of prior art, the Bt talong described in the Mahyco patent could have been obvious to a skilled artisan.

Bt talong is not protected at this time under the Philippine Plant Variety Protection Act, either. Plant varieties understandably are beyond the ambit of the Philippine patent laws, since there is another mechanism, the Plant Variety Protection Act, which serves to provide intellectual-property protection to new plant varieties. The Act provides protection to varieties that are new, distinct, uniform, and stable.[7] The Bt talong varieties developed in cooperation with Mahyco, however, are apparently not protected under this Act at this time. This is no surprise, given that field trials to evaluate the uniformness, stability, and distinctness of the varieties, pursuant to the requirements of the Act, have yet to be completed.

In sum, there is no patent, plant variety protection certificate, or licensing arrangement that enables any particular entity to control the Bt-talong market. In other words, from an intellectual-property standpoint, Filipino farmers should be able to benefit economically from the insect-resistant properties of Bt talong.

[4] See, e.g., Pamela Ronald, Plant Genetics, Sustainable Agriculture and Global Food Security, Genetics 188:11-20 (2011).

[5] See, e.g., Paula M. Davis and Sharon B. Coleman, European Corn Borer (Lepidoptera: Pyralidae) Feeding Behavior and Survival on Transgenic Corn Containing CryIA(b) Protein from Bacillus thuringiensis, Journal of the Kansas Entomological Society 70(1): 31-38 (1997).

[6] See, e.g., U.S. Patent No. 6,072,105, "Insect-resistant transgenic eggplant and method of making."

[7] See Section 4, Republic Act 9168.

PAASE Committee Biosketches

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