ASSESSORS' CONSOLIDATED REPORT ON PIONEER HI-BRED PHILIPPINES AND DOW AGROSCIENCES PHILIPPINES' APPLICATION FOR COMMERCIAL PROPAGATION OF CORN TC1507

EXECUTIVE SUMMARY

On June 06 2018, Pioneer Hi-Bred Philippines and Dow AgroSciences Philippines submitted Corn TC1507 as a new application for commercial propagation to the Bureau of Plant Industry (BPI) under the DOST-DA-DENR-DOH-DILG Joint Department Circular (JDC) No. 1 Series of 2016. After reviewing the Risk Assessment Report and attachments submitted by the applicant the Scientific and Technical Review Panel (STRP), has stated that corn TC1507 is as safe for human food and animal feed as its conventional counterpart.

The Department of Environment and Natural Resources – Biosafety Committee (DENR-BC), after a thorough scientific review and evaluation of the documents related to Environmental Risk along with the submitted sworn statement and accountability of the proponent, recommended the issuance of a biosafety permit for this regulated event provided that the conditions set by them are complied.

The Fertilizer and Pesticide Authority has certified that Pioneer Hi-Bred Philippines is a licensed PIP handler as importer and national distributor and that the company has a legitimate authority to distribute and import the FPA registered PIP product.

Also, the Department of Health – Biosafety Committee (DOH-BC), after a thorough scientific review and evaluation of documents related to Environmental Health Impact, concluded that corn TC1507 will not pose any significant risk to health and environment and that any hazards could be managed by the measures set by the department. DOH-BC also recommended for the issuance of biosafety permit for TC1507.

Furthermore, the Socio-economic, Ethical and Cultural (SEC) Considerations expert also recommended for the issuance of biosafety permit for this regulated article after assessing the socio-economic, social and ethical indicators for the adoption of Genetically Modified Organisms.

BACKGROUND

According to Article VI. Section 15 of the JDC No.1 s2016, no regulated article shall be released for commercial propagation unless: (1) a Biosafety Permit for Commercial Propagation has been secured in accordance with this Circular; (2) it can be shown that based on field trial conducted in the Philippines, the regulated article does not pose greater risks to biodiversity, human and animal health than its conventional counterpart; (3) food and feed safety studies show that the regulated article does not pose greater risks to biodiversity, human and animal health than its conventional counterpart, consistent with CODEX Alimentarius Guidelines on the Food Safety Assessment of Foods Derived from the Recombinant-DNA Plants and protocols of the DOH and BAI on feeding trials; and (4) if the regulated article is a

pest-protected plant, its transformation event that serves as plant-incorporated protectant (PIP) has been duly registered with the Fertilizer and Pesticide Authority (FPA).

The BPI Biotech Office forwarded the complete dossier to the assessors and its respective agencies for their evaluation of the application. Below is the summary of the evaluation conducted by the STRP and regulatory agencies.

STRP ASSESSMENT AND RECOMMENDATION

I. HOST ORGANISM

Corn is one of the most popular cereal grains in the world. Corn is as healthy as any cereal grain, rich in fiber and many vitamins, minerals, and antioxidants According to OECD (2002), corn contains antinutrients such as phytic acid, DIMBOA, raffinose, and low levels of trypsin and chymoptrypsin inhibitors. These chemicals can block the normal uptake or utilization of some nutrients. The STRP cited OECD (2002) who reported that reported that maize has low allergenicity. The Office of the Gene Technology Regulator (OGTR) of the Australian Government (2008) discussed that pollen and maize dust may cause allergies such as hay-fever and baker's asthma, pollen allergen. Maize is considered as one of the oldest cultivated grains and can directly consumed as food at various developmental stages from baby corn to mature grain and can be fed to stock as green chop, dry forage, silage. The corn milling industry, produces several animal feed products such as gluten feed, gluten meal, distillers grains, distillers soluble, germ meal, and hominy, that are economically attainable in specific areas.

II. TRANSGENIC PLANT

The GM corn is not expected to alter the consumption patterns by population subgroups be changed as a result of introducing the novel food. The STRP reports that proponent was able to describe all the protein-encoding sequences found in the original gene construct with respect to source and potential pathogenic or allergenic properties as well as describe all potentially inserted regulatory sequences.

III. THE DONOR ORGANISM

The transformation event contains two genes from different donor organisms. B*acillus thuringiensis* Strain: PS811 (cry1F) is the donor for donor of the *cry1F* gene, while *Streptomyces viridochromogene*s strain Tü494 is the donor of the pat gene. The STRP has noted that the donor organisms has had no history of causing allergy, in over 50 years of commercial use as a microbial pesticide on food crops, there have been no reports of allergenicity to proteins from *Bacillus thuringensis* (Bt), including occupational allergy associated with the manufacture of products containing Bt. These microbial formulations have been used on a wide variety of crops, including fresh vegetables, with no reported allergic concerns. *S. viridochromogenes* occurs widely in nature and is not known to cause allergy. This

history establishes a sound basis for the lack of allergenic potential for the Cry1F and PAT.

IV. TRANSFORMATION SYSTEM

An inbred maize line was transformed with PHI8999A by a micro-projectile bombardment (biolistic) method. TC1507 consisted of an insert at a single genetic locus that included the nearly full-length intact copy of the DNA insert, which contained the cry1F and pat genes. The proponent was able to provide the genetic component used as well as adequately describe the plasmid vector.

V. INSERTED DNA

PHI8999A, a linear DNA fragment containing the cry1F gene and the pat selectable marker gene, was obtained from plasmid PHP8999. TC1507 consisted of an insert at a single genetic locus that included the nearly full-length intact copy of the DNA insert, which contained the cry1F and pat genes. Expression of the Cry1F protein present in genetically modified maize, cotton, and soybean confers resistance to corn borer and other Lepidopteran species.

VI. GENETIC STABILITY

The STPS confirms that Southern blot analyses demonstrated the stability of the inserted genes was studied across at least 6 generations, and inheritance followed a Mendelian segregation pattern for a single dominant gene over multiple generations. Event TC1507 was crossed and backcrossed with an elite inbred to produce hybrids that were tested for glufosinate tolerance and resistance to European corn borer.

The STRP further reports that a 10-bp deletion at the 5' end, a 39-bp deletion at the 3' end was found in the PHI8999A insert in TC1507 maize. A SNP (G to T change) in the CaMV 35S promoter region was observed when compared to the sequence of the PHI8999A. however, the proponent was able to demonstrate the process. The lack of any significant amino acid similarity indicates that the potential for cross-reactivity of either Cry1F or PAT proteins with known allergens is extremely low.

VII. EXPRESSED MATERIAL

The plant-expressed cry1F gene encodes a protein of 68 kDa that is a truncated version of the native protein with a single amino acid substitution (USDA APHIS, 2000). The Cry1F protein is active against certain lepidopterans including key pests such as European corn borer (*Ostrinia nubilalis*), fall armyworm (*Spodoptera frugiperda*), corn earworm (*Helicoverpa zea*), and black cutworm (*Agrotis ipsilon*). It is worth referring to Wolt (2011) for a detailed list of lepidopteran species and observed susceptibilities to Cry1F protein in laboratory studies.

The STRP reports that the Cry1F protein was detected in leaf, root, pollen, stalk, whole plant, and grain tissues. The PAT protein was detected in leaf, root, stalk, whole plant, and grain tissues. The PAT protein was close to the lower limit of the quantitative range of the ELISA in stalk, root, and grain, and was below the lower limit of the quantitative range of the ELISA in pollen. The STRP confirms that The Cry1F and PAT proteins in TC1507 maize have no metabolic role.

VIII. TOXICOLOGICAL ASSESSMENT

Cry1F Protein

Cry1F protein degrades with pepsin, degrading after 15 seconds in SGF as demonstrated by both SDS-PAGE and western blot analysis. The protein loses immunoreactivity after heat processing and degrades quickly under pressures and heat commonly used in commercial processing of maize. Crops containing Bt proteins as in plant insecticides have been grown since 1996 with no reports of adverse health effects. Comparison of Cry1F protein sequence found no similarity to known protein toxins or antinutrients. Acute oral toxicity studies were conducted to assess potential toxicity of the protein and the acute dose (576 mg/kg) represents a value 12,190 times greater than estimated 95th percentile dietary exposure and can be used as a conservative estimate of the margin of exposure.

PAT Protein

SDS-PAGE and western blot analyses results demonstrated that PAT protein was digested to non-detectable levels within 5 seconds after addition of SGF containing pepsin. As the PAT proteins are readily digested by pepsin, there is a lower probability they would cause adverse health effects due to limited persistence in the mammalian digestive environment. When heated at 55 °C for 10 min, the PAT protein was denatured as corroborated by a loss of enzymatic activity. No homologous alignments between the PAT protein sequence and any protein sequence was reported. Safety of PAT protein was also demonstrated in a 2-week acute oral toxicity study in mice. All mice survived the 2-week study and there were no treatment-related clinical observations of toxicity.

Potential Interaction

The cry1F and pat gene coding sequences were driven by regulatory sequences enabling constitutive expression of the Cry1F and PAT proteins throughout the plant. TheCry1F protein was detected in leaf, root, pollen, stalk, whole plant, and grain tissues. The PAT protein was detected in leaf, root, stalk, whole plant, and grain tissues.

The two proteins do not interact to express the phenotype and the protein products of the inserted genes (cry1F and pat) are not in any way, proteins that regulate the normal metabolic pathways of plants and therefore will not interfere with the plant's normal growth and development. The two proteins have different modes and/or mechanisms of action and binding sites involved for each protein.

IX. ALLERGENICITY ASSESSMENT

Cry1F Protein

Cry1F protein hydrolyzed within one minute in pepsin SGF as demonstrated by both SDS-PAGE and western blot analysis and loses immunoreactivity after heat processing and degrades quickly under pressures and heat commonly used in commercial processing of maize. Bioinformatics analyses were conducted to compare whether the amino acid sequences of Cry1F and PAT proteins are similar to sequences in a database of food, dermal, and respiratory allergenic proteins. Such in silico analyses additionally examine the potential for cross-reactivity to

known allergens. The lack of any significant amino acid similarity indicates that the potential for cross-reactivity of Cry1F proteins with known allergens is extremely low. The percent of total protein of the Cry1F protein in maize is 0.38%

PAT Protein

As the PAT proteins are readily digested by pepsin, there is a lower probability they would cause adverse health effects due to limited persistence in the mammalian digestive environment. When heated at 55 °C for 10 min, the PAT protein was denatured as corroborated by a loss of enzymatic activity. No homologous alignments between the PAT protein sequence and any protein sequence was reported. The percent total PAT protein would be 0.000065%

X. NUTRITIONAL DATA

According to the study conducted, there is significant difference in the percentage fat between the transgenic line and the comparator, but values are within the range of literature values. All statistical differences are not biologically relevant and, Antinutrient of TC1507 maize is comparable to non-GM line maize and no significant difference observed in this respect. Phytic acid and raffinose levels are within the reported range. Trypsin inhibitor is below the reported range because of limited quantity of enzyme used during the analysis.

XI. THE HOST PLANT ENVIRONEMENT

Maize is a cross-pollinated crop relying on wind for the dispersal of its pollen. Although maize is not an insect pollinated crop, flower visiting insects that feed on nectar and pollen may have the potential to transfer pollen from the male parts of the flower to the female parts of the flower. Lit et al (2012) were able to monitor the following pollinators: common syrphid flies (*Ischiodon scutellaris*), hover flies (*Metasyrphus sp.*), stingless bees (*Tetragonula sapiens and Trigona sp*.), carpenter bees (*Anthrophoridae*), adult rat-tail maggots (*Eristal*i *sp.*), and bee flies (*Bombylidae*). They also observed butterflies like *Eurema hecabe* and *Leptosia nina*. Malourba-Souza (2011) concluded that maize is a food source of honeybees. The study conducted by Anderson (2012) on honeybees fed by Cry1F protein equivalent revealed that there is no effect on the survivability of the honeybee larvae.

Possible formation of viable interspecific and between domesticated maize and Tripsacum species is unlikely under natural field conditions.

ISAAA (2016) reported that the “Philippines continues to be at the forefront of biotech research and commercialization in South East Asia and has a model for science-based and thorough regulatory policy in the region”. This may entail that GM crops are accepted in the country. No changed in cultivation practices have been recorded in the country. Maize in the Philippines are grown in areas where they are suitable. According to the study conducted by Anderson J (2012), testing site where in the major growing regions of the country. The applicant was able to provide enough evidence to prove their claim. Samson et al (2012) was able to provide enough evidence to prove that there is no genetic modification resulted in an altered reaction to pests and/or diseases. The STRP has listed common associated pests and diseases to the crop.

XII. THE CONSEQUENCES OF OUTCROSSING

It has been established that maize event TC1507 is substantially equivalent when compared with its non-GE counterpart. Cultivation of TC 1507 maize poses negligible risk to the environment as a weed. Outcrossing between domesticated maize and Tripsacum species is unlikely under natural field conditions (OECD, 2003; US EPA,2001). None of the genetic modifications in TC1507 maize were intended to alter the agronomy or composition of the TC1507 maize, relative to non-GE maize. As the agronomic characteristics were comparable between TC1507 maize and non-GE maize, there is no evidence to suggest that TC1507 maize has different reproductive biology or would not be subject to the same environmental and genetic barriers to gene flow as conventional maize. As such, no mitigation measures have been established to mitigate the risks from out-crossing.

XIII. WEEDINESS POTENTIAL

Dissemination of the crop is through viable seeds.

XIV. SECONDARY AND NON-TARGET EFFECTS

Field Studies by Lit et al (2012) were cited in the assessment of the effect of the regulated article on secondary and non-target insects and arthropods. The study was conducted in Cauayan Isabela and Tampakan, South Cotabato during the 2011-2012 wet and dry cropping seasons and sampling was done using the sweep net method.

Collembola were not affected by chronic exposure to Cry1F at the treatment levels. Treatments used in study exceeded worst case estimates, indicating that the risk to springtails under field conditions is negligible. The STRP reported that the test insect is a common species of springtails that is present in the soil throughout the world.

Earthworm (*Eisenia fetida*), No mortality was observed at tested concentration over the 14-day study indicating that earthworms are at negligible risks to the environment.

Parasitic Hymenoptera (*Nasonia vitripennis*) Nasonia vitripennis has a worldwide distribution, and has presumably spread around the world due to its use of human associated flies. No increased mortality or treatment-related effects were observed at tested concentration.

Green Lacewing (*Chrysoperla carnea*) No increased mortality or treatment-related effects were observed at tested concentration.

Honeybee (*Apis mellifera*), is a native honeybee in Europe but now found all throughout the world, No effects on larval survival were observed in honeybees fed Cry1F protein equivalent to a 10X field exposure.

Water Flea *(Daphnia magna),* No mortality or treatment-related effects were observed at the 100 mg Cry1F pollen treatment. The EC50 for D. magna exceeds the worst-case environmental exposure estimate by several order magnitudes,

indicating that Cry1F protein poses no hazards to *Daphnia* at environmentally relevant concentrations.

Pollinators observed in trials include the syrphid fly, *Ischiodon scutellaris*; and the hover fly, *Metasyrphus* sp. Pollinators also include the palynovores (pollen-feeders) represented by the stingless bee, *Tetragonula sapiens* which were abundant in TA, especially during the pollen shedding stage. Some species sighted in the field include an Anthophoridae (carpenter bee), adults of rat-tail maggots (*Eristalis* sp.) and bee flies (Bombyliidae).

The sucking herbivores observed were the corn leaf aphid, *Rhopalosiphum maidis*; several corn leafhoppers: *Dalbulus* sp., *Nephotettix* spp., *Nezara viridula*; corn planthoppers, *Peregrinus maidis* and *Stenocranus pacificus;* and the less common moth hopper, *Ricania* sp.

Non-target chewing herbivores identified were flea beetle, *Phyllotreta* sp.; (Figure 27.B); squash beetle; silk beetle; flower beetle; June beetle; horned coreid bug, *Cletus trigonus*; rice bug, *Leptocorisa oratorius*; and a pachyrrhynchid weevil, *Metapocyrtus* sp.

The following Non-Target Arthopods species observed:

- Coccinellids or ladybird beetles: *Micraspis discolor* and *Chilomenes sexmaculata*
- Predatory tiny black beetle, *Phalacrus* sp.; orange lady beetle, *Chilomenes sexmaculata*; rove beetles; tiger beetle; net-winged beetle; hispine black beetle; earwigs
- Mirid bugs, *Cyrtorhinus lividipennis*; bigeyed bug, *Geocoris* sp.; damsel and pentatomid bug.
- Predatory black cricket, *Metioche vittaticollis* and the long-legged flies.
- Lacewings, *Micromus igorotus* and *Mallada basalis*
- Syrphid fly, *Ischiodon scutellaris*
- Dragonflies and damselflies, *Pseudagrion* sp.; the slender skimmer, *Orthetrum Sabina*; and common ground skimmer, *Diplacodes trivialis*.
- Spiders: Lynx spiders; Lycosids, *Pardosa pseudoannulata*; derby spider, *Neoscona* spp; corn spider, *Argiope* sp.; and other spiders belonging to at least six families.
- Ants: *Solenopsis geminate* and *Pheidologeton diversus*

After a thorough and scientific evaluation of the documents provided by the applicant, relevant to the application for commercial propagation of Corn TC1507, the STRP finds scientific evidence that the regulated article will not pose any significant to human and animal health.

DA-IRMAT AND RECOMENDATION

The DA Insect Resistance Management Advisory Team (IRMAT) reviewed the submission of Pioneer Hi-Bred Philippines Inc. For the new application for a

commercial propagation under the DOST-DA-DENR-DOH-DILG JDC No.1 s2016 of Corn TC1507 and Corn MON810 x TC1507 x NK603 through *ad referendum.*

Having been mandated by the DA Special Order No. 24 s2017 to provide advice and direction to the BPI in matters relating to Insect Resistance Management (IRM), after a review of both applications, the IRMAT therefore finds that the applicant's submitted documents with substantial compliance with the previously issued DA Memorandum Circulars pertaining to IRM.

FPA EVALUATION AND RECOMMENDATION

Based in the FPA records, Pioneer Hi-Bred Philippines Inc., registrant of TC1507, is a duly licensed national distributor and importer of Plant-incorporated Protectant (PIP) with Licenses No. PIP-PIP-ND-00001) respectively, that are valid until November 9, 2019. However, the operation as manufacturer and formulator of PIP will commence upon final inspection/evaluation on December 17, 2018.

The protein *Cry1F* contained in the corn event of TC1507 has been issued with e Full PIP Product Registration (Reg. No. PIP-03-04-05) by FPA on October 25, 2018, which will expire on October 25, 2021. This is in compliance with the rules and regulations of the FPA Memorandum Circular No. 10, Series of 2017, Guidelines of the Registration of Plant-incorporated Protectants (PIPs) in Pest-Protected Plants (PPPs) with Pesticidal Action derived from Modern Biotechnology.

Results of Evaluation of the data supporting studies for Cry 1F protein in TC1507 corn showed that it is scientifically well studied for its efficacy against targeted Lepidopteran pests of corn. Studies have also shown that there is a high margin of safety associated with the ingestion of Bt protein Cry1F, as the protein is easily degraded by digestive chemicals, negligible allergenic potential, improbable chronic exposure scenario and good safety profile from several years of "massive" use (or propagation) and consumption by the general public. With regard to the environmental safety of Cry 1F, studies have shown that Cry1F does not pose a significant harm and risk to non-target insects, arthropods, and other organism in the field. The residues of cry1F protein from TC1507 maize is exempted from the establishment of residue limits, as its corresponding proteins are fully digestible in simulated gastric fluid. The US EPA had granted tolerance exemption for the PIP of Bt proteins Cry 1F due in 2001 due to lack of human health effect.

Moreover, Pioneer Hi-Bred Philippines is a licensed PIP handler as importer and national distributor. The company has a legitimate authority to distribute and import the FPA registered PIP product TC1507.

Therefore, with the support of reliable international technical studies and FPA official evaluation reports, it can be concluded that the PIP Cry1F in TC1507 corn is compliant with the requirements for licensing GAP and tolerance.

DOH-BC ASSESSMENT AND RECOMMENDATION

After a thorough review and evaluation of the documents provided by the proponent, Pioneer Hi-Bred Philippines, Inc. and Dow AgroSciences Philippines

through the Bureau of Plant Industry (BPI), in support of their application for approval for Direct Use for Food and Feed or for Processing (FFP) of Corn TC1507 the DOH-BC find that the regulated article applied for Direct Use for Food and Feed or for Processing (FFP) is safe as its conventional counterpart and shall not pose any significant risk to human and animal health, and environment.

The following are the observations and recommendations:

1. Find that the regulated article applied for Commercial Propagation (CP) does not require changes in the usual practices as described in the phases/stages of biotechnology project activities. As such, the regulated article is as safe as its conventional counterpart and is not expected to pose any significant risk to human and animal health and environment.

2. Scientific pieces of evidences from Toxicity studies and references, find that the regulated article will not cause significant adverse health effects to human and animal health

3. Dietary exposure to the regulated article is unlikely to result allergic reaction.

4. The regulated article is not materially different in nutritional composition from that of the non-transgenic corn or the conventional corn.

5. Scientific pieces of evidences from provided references i.e. literatures, show that regulated article applied for Commercial Propagation is as safe as its conventional counterpart and shall not pose any significant risk to human and animal health and on the environment.

6. It is suggested that the Bureau of Plant Industry (BPI) ensure the following :

    a. Strict monitoring trader's/importer's series, 2016.of the regulated article from port of entry to the storage/warehouse as stated in Section 32 of the JDC No. 1 s2016

    b. The BPI to include in the issuance of permit for the release of this product the following conditions :

        b.1. Any spillage (during unloading and loading/hauling and transport unloading and storage) shall be collected and cleaned up immediately.

        b.2. Transportation of the consignment from the port of entry to any destination within the country shall be in closed containers.7. Based on the above considerations and with the submitted sworn statement and accountability of the

proponent, this recommendation is being submitted to BPI related to the processing and issuance of a Biosafety Permit for Commercial Propagation (CP) of Corn TC 1507.

DENR-BC ASSESSMENT AND RECOMMENDATION

After a comprehensive review and evaluation of the documents, including scientific evidence from references and literature submitted by Pioneer Hi-Bred Philippines, Inc. And Dow Agro Sciences on its application for Commercial Propagation of Corn TC1507, hereunder are the observations and appropriate actions:

1. The regulated article is considered substantially equivalent to its conventional counterpart for its history of safe use as food in twenty-two (22) countries and as feed in seventeen countries. It has also been previously approved for commercial propagation in twelve (12) countries (ISAAA, 2017)

2. The genetic stability of the transgenic crop was tested over multiple generations wherein the hybrids of the regulated article crossed and backcrossed with inbred were tested for glufosinate herbicide resistance and insect resistance. Furthermore, through southern blot analysis, the progenies across 6 generations were analyzed to verify the stability of the inserted genes, in which it follows a Mendelian Segregation pattern for a single dominant gene.

3. The insect resistance and herbicide tolerance traits of the regulated article do not alter nor enhance the persistence, invasiveness, or weediness of the crop relative to its conventional counterpart and;

4. Hazard studies as summarized by Baktavachalam et al (2015) on non-target organisms were conducted to different surrogate species of pollinators and pollen feeder of corn plant. The study demonstrates that the exposure to Cry1F proteins at concentrations exceeding the realistic environmental concentration poses low hazard on non-target organisms. This indicates that TC1507 has no negative effects on the corn-associated arthropod biodiversity of corn fields.

The DENR-BC therefore considers the regulated article to be safe to the environment and biodiversity, particularly non-target organisms and hereby submits the technical report relative to the application of Pioneer Hi-Bred Philippines, Inc. And DowAgroSciences Philippines for a Biosafety Permit for commercial propagation of Corn TC1507.

SEC EXPERT ASSESSMENT AND RECOMMENDATION

TC1507 was not commercialized as a single product but rather as a component of stacks, including Intrasect® (MON810XTC1507XNK603). Corn containing TC1507 is expected to help protect the yield and help prevent decrease in productivity due to more effective control of Asiatic corn borer, the most destructive insect pest of corn in the Philippines, as well as certain secondary lepidopteran corn pests.

The benefits of planting Intrasect was already evident from the results of regulated trials conducted to verify the field performance of Intrasect (Samson et al., 2012; Samson and Caasi-Lit, 2012)

Following biosafety approval of Intrasect in 2013, Pioneer conducted "Side by Side" Trials for customer showcase and from which data were generated for direct comparison of Intrasect crop and its non-GM counterpart with the same genetic background. These trials were conducted in Isabela and North Cotabato each with seven sites in the wet and dry seasons of 2014.

The answers provided here are based on data generated internally from a set of trials conducted in 2014. A total of 28 side-by-side trials (7 locations during the wet and dry seasons in Isabela and South Cotabato) were conducted a year after Intrasect was approved in 2013 and before commercial launch to support the decision to commercialize. The widely adopted conventional hybrid P3774 and its GM version P3774YHR were used in these studies. Based on the positive results as presented here, no additional post-commercialization study or actual farmers' field survey on the economics of planting Intrasect was conducted. The fact that farmers have opted to plant Bt crops is a testament of the economic benefits that they continue to enjoy from cultivating these products.

After a thorough and scientific review and evaluation of the documents provided by the applicant for Corn TC1507 for Propagation, I recommend for the approval and issuance of biosafety permit of the said GM product.

The proponents should take note however that if TC1507 is approved for commercial release, and would apply for renewal in the future, 5 years after its approval for commercial use, the proponents should present actual socio-economic field data from farmers' field in at least 3 major corn producing provinces in three regions for 2 crop years (four seasons), taken within the 5 year period.

IRM STRATEGY FOR MON810xTC1507xNK603 (INTRASECT®)

Guided by the official issuances from the DA-Bureau of Plant Industry on insect resistance management (IRM), Pioneer is committed to and has been implementing insect resistance monitoring, a key component of a robust IRM program.

Since Intrasect® contains a dual mode of action for insect control provided by Cry1Ab protein (produced by event MON810) and Cry1F protein (produced by event TC1507), refuge for this product is deployed as 5% refuge-in-a-bag (RIB) or blended with the main product. The 5% blended refuge in stack Bt products is intended to facilitate refuge compliance by the farmers while protecting durability of these Bt proteins.

Pioneer implements and complies with the key elements of the IRM program, including:
(1) reporting of seed sales every season, (2) establishment and monitoring of sentinel sites for ACB damage, (3) detection of changes in susceptibility with routine diagnostic dose assays, (4) investigating unexpected insect damage reports by growers, (5) implementing seasonal field training activities for farmers, and (6)

conduct of bi-annual survey on farmers' knowledge, attitude and practices on IRM, and conduct of other IRM-related studies.

1. Reporting of seed sales every season

Pioneer submits to the DA-BPI a seasonal adoption report covering the different corn growing regions in the country based on the sales of Bt-traited seed sales. Also submitted every season is a list of IRM trainings conducted nationwide during the period. Reports for the dry season are submitted on or before March 25 while reports for the wet season are submitted on or before August 25 of each year.

2. Establishment and monitoring of sentinel sites for ACB damage

The seed companies selling Bt corn in the country are working together to comply with the requirement to establish and monitor actual ACB damages in the field to determine any resistance development. Based on the agreement with other seed companies, Pioneer maintains four sentinel sites for its two Bt corn products: MON810xNK603 and MON810xTC1507xNK603. These sites are located in Tumauini and Echague, Isabela; Magalang, Pampanga (dry season only); and Koronadal, South Cotabato.

3. Detection of changes in susceptibility with routine diagnostic dose assays

The seed companies are jointly supporting a project being implemented by the team of Dr. Edwin Alcantara of BIOTECH, UPLB for the monitoring of possible changes in the susceptibility of ACB to various Bt proteins through routine protein diet bioassay using diagnostic doses. Like the other seed companies, Pioneer submits every season sufficient number of field-collected ACB from its areas of assignment to the team of Dr. Alcantara. Purified Bt proteins are also provided by Pioneer for the monitoring activity.

4. Investigating unexpected insect damage reports by growers.

Farmer field surveillance is an important component of an effective resistance monitoring plan because it provides early warning of pest adaptation. Pioneer follows up on all customer calls about product performance. Stewardship of our current products and future products is key to our customers' success. Pioneer has an established process to receive and investigate all customer inquiries related to product performance. This process includes grower2 interviews, field investigations and when necessary, the collection and subsequent evaluation of insects from fields under investigation using a discriminating dose of the protein. If resistance is confirmed using this process, additional research including confirmation of heritability would be completed.

5. Conduct of bi-annual survey on farmers' knowledge, attitude and practices on IRM,and conduct of other IRM-related studies.

Pioneer is coordinating with the other seed companies for the conduct of a nationwide survey every two years on farmer knowledge, attitudes, and practices

on Bt corn farming to monitor compliance with IRM. This is a post-approval requirement by the government for all Bt corn products. Such big gatherings of farmers are used as an opportunity to disseminate key IRM messages to the farmers after the survey has been conducted. New research as may be required by the regulators are conducted to learn more about how to contribute to our customers' success and preserve the value of Bt traits. Some of this work includes implementing IRM related studies to validate assumptions and strengthen IRM policies. These studies include bioefficacy using leaf tissues and whole plants, larval movement in the screenhouse and in the field, adult dispersal in the field, and mating behavior of ACB.

References:

1. DA Memo Circular 04 s2007 "Revised procedural guidelines and templates for Bt IRM monitoring and reporting"
2. DA Memo Circular 17 s2003 "Additional Requirements for IRM Strategy in Bt Corn"
3. DA Memo Circular 03 s2012 "New Directive on IRM in Bt Corn"
4. DA Memo Circular 02 s 2014 "Enhancing the IRM strategy of Bt corn targeting ACB