

**RISK ASSESSMENT REPORT  
OF THE GENETIC MODIFICATION  
ADVISORY COMMITTEE (GMAC)**

***FOR***

**AN APPLICATION FOR APPROVAL FOR RELEASE  
OF PRODUCTS OF TC1507 CORN FOR SUPPLY  
OR OFFER TO SUPPLY**

**NBB REF NO: JBK(S) 602-1/1/6**

**APPLICANT:DUPONT MALAYSIA SDN. BHD.**

**DATE SUBMITTED:10 MAY 2012**

## ***I - Summary of Assessment Process***

The Genetic Modification Advisory Committee, under the purview of the National Biosafety Board, was given the dossier by the Department of Biosafety on 24 May 2012 for an application for approval for importation for release (sale/placing on the market for direct use as food, feed and for processing (FFP)) of a product of a Living Modified Organism (insect-resistant and herbicide-tolerant TC1507 corn). The application was filed by Dupont Malaysia Sdn. Bhd. (hereafter referred to as “the applicant”). GMAC members also took the opportunity to obtain further clarification on certain details of the activity. Additional information was provided by the applicant as requested. Please refer to **Lampiran IB** for Additional Information provided by the applicant.

A public consultation for this application was conducted from 8 August 2012 to 6 September 2012 via advertisements in the local newspapers. A few technical and scientific issues were raised through the Public Consultation for this application regarding the release. These issues have been considered by GMAC in the risk assessment.

GMAC had three meetings pertaining to this application and prepared the Risk Assessment Report and Risk Assessment Matrix along with its recommended decision, for consideration by the National Biosafety Board.

## ***II - Background of Application***

This application is for approval to import and release products of a Living Modified Organism TC1507 (insect-resistant and herbicide-tolerant corn). The aim of the import and release is to supply or offer to supply for sale/placing on the market for direct use as food, feed and for processing (FFP). According to the applicant, TC1507 has been registered in a number of countries for cultivation as well as for importation for direct use as feed and for processing corn. TC1507 corn is grown in a number of countries, e.g. United States, Canada, Argentina, Philippines, Brazil and South Africa, and may be imported, stored and processed for use in food, animal feed and industrial products in the same way as other conventional, non transgenic corn. The type of expected use of the products derived from TC1507 corn in Malaysia will be the same as the expected usage for products derived from conventional corn. Potential users of products derived from TC1507 corn such as grains are feed millers, food processors and other industrial use.

### **Information about TC1507 corn**

The recipient or parental plant is *Zea mays* L.spp *mays* (field or sweet corn). Corn is extensively cultivated and has a long history of safe use as a food or feed. It is the world's third leading cereal crop behind wheat and rice.

TC1507 corn has been genetically modified (GM) by incorporation of two bacterial genes: the *cry1F* gene (derived from the soil bacterium *Bacillus thuringiensis* var. *aizawai* strain PS811) which expresses an insect-specific protein toxin, Cry1F, and the *pat* gene (derived from the soil bacterium *Streptomyces viridochromogenes*) which expresses the enzyme phosphinothricin acetyltransferase (PAT), conferring tolerance to glufosinate-ammonium herbicides.

Cry1F protein, as expressed in TC1507 corn, is effective in controlling European Corn Borer (*Ostrinia nubilalis*), southwestern corn borer (*Diatraea grandiosella*), black cutworm (*Agrotis ipsilon*) and armyworms (*Spodoptera* sp.) that are common insect pests of corn in the USA where this variety is intended to be primarily cultivated.

TC 1507 is also tolerant to glufosinate-ammonium herbicide through the expression of a bacterial gene from *Streptomyces viridochromogenes*, encoding an enzyme, phosphinothricin acetyltransferase (PAT). This enzyme is able to specifically break down the herbicide in the plant, converting it to an inactive form, thus allowing the plants to grow normally. The production of PAT in the plants allows selection of GM plants in the field as well as providing tolerance to the herbicide when used at agricultural levels.

### **III - Risk Assessment and Risk Management Plan**

GMAC evaluated the application with reference to the following documents:

- (i) CODEX Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants.
- (ii) Roadmap for Risk Assessment of Living Modified Organisms, (according to Annex III of the Cartagena Protocol on Biosafety produced by the *Ad Hoc* Technical Expert Group (AHTEG) on Risk Assessment and Risk Management of the Convention on Biological Diversity).
- (iii) The risk assessment and risk management plan submitted by the applicant.

GMAC took cognizance of the following as suggested within the AHTEG guidelines:

- (i) That the risk assessment exercise be specific to the details of this particular application
- (ii) That the risk assessment exercise be specific to the receiving environment in question, and

- (iii) That any risk identified be compared against that posed by the unmodified organism.

A Risk Matrix was prepared based on an assessment mechanism developed by Office of the Gene Technology Regulator, Australia (OGTR, 2009). In applying this matrix, GMAC identified potential hazards, and then added a value/rank for the likelihood of each hazard as well as its consequences. The likelihood of each hazard occurring was evaluated qualitatively on a scale of 1 to 4, with 1 for 'highly unlikely', and 4 for 'highly likely'. The consequences of each hazard, if it were to occur, were then evaluated on a scale of 1 to 4, with 1 for 'marginal' and 4 to denote a 'major consequence'. A value was finally assigned for the overall risk from the identified potential hazard. The general formula: Overall Risk = Likelihood x Consequence was employed. GMAC also proposed risk management strategies for potential hazards, where appropriate. This methodology of assessment follows the procedure of Risk Assessment in Annex III of the Cartagena Protocol on Biosafety.

The Risk Assessment was conducted over a series of three meetings. To start with, the possible pathways to risk/hazard arising from release of the products were identified and listed. The potential hazards were identified in three main areas:

(i) **Effects on human health**

Relevant scientific publications on TC1507 corn were reviewed for potential human health risks and issues pertaining to acute toxicity of the novel proteins, potential allergenicity, mutagenic/teratogenic/carcinogenic effects, reproductive toxicity, potential transfer of antibiotic resistance genes in the digestive tract, the pathogenic potential of the donor microorganisms, nutritional equivalence and anti-nutrient activity.

(ii) **Effects on animal health**

Issues pertaining to allergenicity, toxicity, survivability, horizontal gene transfer, anti-nutritional properties, compromised nutritional content.

(iii) **Effects on the environment**

Issues pertaining to unintentional release and planting, weediness, gene transfer to bacteria, accumulation of the Bt toxin, cross-pollination and toxic effects on non-target organisms were examined.

Based on the above, a final list of 22 potential hazards was identified. Most of these hazards were rated as having an Overall Risk of 1 or "negligible" (please refer to the **Lampiran IIB/Risk Matrix** for details). In addition safety assessment reports from several government regulatory

agencies, namely Australia, Canada, European Union and Philippines were referred to. The safety assessment reports were based on studies conducted by independent experts on the molecular characterization, biochemical, toxicological, nutritional, and allergenicity data of the introduced proteins, in accordance with guidelines from World Health Organization (WHO), the Food and Agriculture Organization (FAO) and the Codex Alimentarius Commission. These data have showed the stability of expression of Cry1F and PAT protein. While a number of putative Open Reading Frames (ORFs) adjacent to the gene insertion site were detected using bioinformatics, none of these appears to encode sequences with similarity to known allergens or toxins. There are also no indications that any of these ORFs are transcriptionally active.

GMAC also took extra caution and further discussed pre-emptive mitigation procedures for hazards where the Overall Risk was estimated to be above the minimal, and also for a few hazards that required further evaluation and data acquisition. Some of these risks are expected to be managed effectively with the risk management strategies proposed (please refer to section IV of this document).

A few potential hazards where the Overall Risk was found to be 2 or “low” are highlighted below along with the appropriate management strategies (please refer to **Lampiran IIB/Risk Matrix**).

**a) Accidental release of viable seeds**

Seeds may be accidentally released during transportation and these spilled seeds may germinate and become established in the ecosystem. Spillage of seed is likely, however, it is unlikely that these spilled seeds will germinate and become established in the ecosystem as the post-harvest drying process of forcing hot air through the grains (seeds) would affect the viability of the seeds. Furthermore, corn generally does not survive well without human cultivation. It is an annual plant. Outcrossing with any locally cultivated corn or wild relative of corn is unlikely as corn is not grown as an economic crop in Malaysia and there is no wild relative. However, as some baby corn and sweet corn are grown in this country, there is a likelihood of outcrossing of the GM corn with these. As spillage of seed during transportation is likely, it is proposed that a post monitoring plan should be implemented and any spillage incident should be managed.

**b) Planting of seeds**

Plants may be grown through the ignorance of uninformed farmers and perpetuated through small scale cultivations. It is noted that the post-harvest drying process of forcing hot air through the grains, affects the viability of the corn grains. Corn is not a major crop in Malaysia. Nevertheless, there could be persistence of GM crop plants in the environment, albeit at low

level. These GM corn may pollinate the non-GM baby corn and/or sweetcorn. It is proposed that a post monitoring plan should be implemented and any spillage incident should be managed. There should also be clear labeling of the product to state that it is only for the purpose of food, feed and processing, and is not to be used as planting material.

**c) Compromised Nutritional Content**

Maize 1507 is as nutritious as the non-GM counterparts (EFSA, 2009). Studies show no statistically significant differences in nutritional performance variables and organ weights were observed between Sprague–Dawley rats fed TC1507 corn grain and those fed three non-GM corn control diets (MacKenzie et al., 2007). Usage of maize silage and maize kernels derived from transgenic 1507 maize and non-GM control hybrids showed no significant differences on feed intake and milk production of 20 lactating dairy cows (EFSA, 2005). No significant differences in body weight, body weight gain and feed conversion between broilers fed GM 1507 maize, control hybrid maize Mycogen 7250 and four commercial maize hybrids (EFSA, 2005). However, applicant is required to update NBB immediately if additional tests indicates potential adverse effects or the possible presence of toxin or allergen proteins.

**IV - Proposed Terms and Conditions for Certificate of Approval**

Based on the 22 potential hazards identified and assessed, GMAC has drawn up the following terms and conditions to be included in the certificate of approval for the release of this product:

- a) There shall be clear documentation describing the product by the exporter which shall be declared to the Customs of the importing country.
- b) Any spillage (during loading/unloading) shall be collected and cleaned up immediately. The approved person shall submit a yearly report to the National Biosafety Board in compliance with procedures for handling any spillage
- c) Transportation of the consignment from the port of entry to any destination within the country shall be in closed containers.
- d) A post monitoring plan for reporting adverse health effects in human and animals shall be implemented.
- e) Should the approved person receive any scientifically proven information/evidences that confirms any adverse effect of TC1507 corn, the National Biosafety Board authority shall be informed immediately for a review (as in Section 18 of the Biosafety Act).
- f) There shall be clear labeling of the product from importation down to all levels of marketing stating that it is only for the purpose of food, feed and processing and is not to be used as planting material.

## ***V - Other Regulatory Considerations***

- a) Administrative regulatory procedures shall be arranged between the Department of Biosafety, Royal Malaysian Customs Department and relevant agencies to ensure accurate declaration of product information and clear labeling of the product is implemented.
- b) Administrative regulatory procedures shall be arranged between the Department of Biosafety and the Malaysian Quarantine and Inspection Services (MAQIS) to impose post entry requirements for accidental spillage involving the GM product.
- c) Administrative regulatory procedures shall be arranged between the Department of Biosafety and the Malaysian Quarantine and Inspection Services (MAQIS) and other competent agencies to impose post entry requirements for food safety compliance.
- d) Administrative regulatory arrangements shall be carried out between the Department of Biosafety and the Department of Veterinary Services (DVS) so that any unanticipated adverse effects in animals caused by any consumption of the GM products shall be reported immediately.
- e) Applicant is responsible to ensure that the user and/or importer of the technology are aware of the Terms and Conditions for Certificate of Approval as given in Section IV.
- f) The necessary authorities should conduct regular checks on imported corn, local meat (animals fed on these) and imported meat (from countries with this GMP or importing it) to ensure compliance with safety limits of glufosinate residues. There are legal limits on levels of glufosinate that are allowed. Seeds are exposed less to pesticides. Glufosinate and metabolite MPPA3 (3-methylphosphinicopropionic acid) are neurotoxins. Teratogenic and animal studies show that it has reproductive toxicity; and is a skin and eye irritant. However, it is excreted in urine and faeces. Recommended management strategy is initial checks on random batches for residue levels at port of entry.

## ***VI - Identification of issues to be addressed for long term use release of this product***

No additional issues have been identified that would be important during the assessment of an application for the long-term usage of this product. Continuous monitoring is required from the approved person to report any unanticipated adverse effect caused by the TC1507 corn.

## ***VII –Conclusion and Recommendation***

GMAC has conducted a thorough evaluation of the application for approval for importation for release (sale/placing on the market for direct use as feed and for processing (FFP)) of a product of a Living Modified Organism (insect-resistant and herbicide-tolerant TC1507 corn) and has determined that the release of this product does not endanger biological diversity or human, animal and plant health. GMAC recommends that the proposed application for release be **APPROVED WITH TERMS AND CONDITIONS** as listed in section IV - Proposed Terms and Conditions for Certificate of Approval.

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