NATIONAL BIOSAFETY AUTHORITY

GM FOOD/FEED SAFETY ASSESSMENT REPORT

REVIEW OF THE FOOD/FEED SAFETY ASSESSMENT DATA PROVIDED IN THE APPLICATION FOR ENVIROMENTAL RELEASE, CULTIVATION AND PLACING ON THE MARKET OF INSECT PROTECTED MON 810 MAIZE AND ITS VARIETAL DERIVATIVES IN KENYA

Background

The National Biosafety Authority received an application for the environmental release, cultivation and placing on the market of insect protected Mon 810 Maize and its varietal derivatives in Kenya.

The food/feed safety assessment review was guided by well-established internationally accepted principles developed by the Codex Alimentarius Commission (CAC) and other competent bodies for the safety evaluation of foods and feed derived from genetically modified organisms, and Authority's opinion will be provided therein.

The scope of this review is to give an opinion of the safety of MON 810 maize if it is to be used as a food and/or food ingredient produced from the maize, as feed consisting of and /or containing the maize, and food and feed additives, and feed materials produced from the maize.

Introduction

The MON 810 maize was genetically modified to encode cry1Ab gene from *Bacillus thuringiensis (Bt)* resulting into the event MON810 so as to express an insecticidal crystal protein, Cry1Ab. The goal of the review therefore is to assess whether the documentation presented demonstrates that MON 810 maize is not substantially different from conventional maize and therefore not likely to pose any food safety issues if handled, processed and consumed normally. Following well established guidelines, the food safety issues evaluated are categorized as follows (i) General safety issues; (ii) Toxicology issues; (iii) Allergenicity issues; (iv) Nutritional issues.

Safety Assessment

1. General Safety

In outlining general safety issues relating to the MON 810 the applicant was required to demonstrate the following:

a. History of safe us of the donor organism and the recipient organisms in this case *Bacillus thuringiensis (Bt)* and maize respectively.
b. No changes at the gene level other than the insertion of *cry1Ab* gene and stability of the introgression that may lead to unintended expressions and therefore unintended effects.

The information presented indicates that there is a history of safety of the recipient organism, history of safe consumption of maize, humans have been exposed to the donor organism, *Bacillus thuringiensis* occurs in the national habitat, and also that its insecticidal products have been used as bio-pesticide for over half a century.

Molecular characterization information demonstrates that only cry1Ab gene was inserted and that it was stably integrated. This is necessary as it is a predictor of unintended effect.

2. Toxicology

The nature and function of any new proteins in a GM food was examined as part of the assessment process. In evaluating the safety of the inserted protein as far as toxicity the following information should be required:

a. History of safe use or human exposure to the new protein.

b. Amino acid sequence homology comparison of the newly expressed protein and known protein toxins and anti-nutritive factors.

c. Demonstrate the susceptibility of each newly expressed protein to pepsin digestion.

d. Acute oral toxicity study(s) for the newly expressed proteins.

e. Where a host other than transgenic plant is used to produce sufficient quantities of the newly expressed protein for toxicological analyses, demonstrate the structural, functional and biochemical equivalence of the non-plant expressed protein with the plant expressed protein.

The applicant provided data and evidence on all the above toxicological assessment elements except for item (e). However (e) was presumed to have been done based on known best practices for conducting toxicity studies. The applicant was requested to provide this addition information for the record.

As far as toxicological issues are concerned it is the Authority's opinion that there is no evidence Cry1Ab protein would be toxic. The source of the cry1Ab gene has a long history of

use on food crops as a bio-pesticide with no report of adverse effects. The data provided indicates that the protein has no amino acid similarity to known toxins and is expressed at a relatively low level in Mon 810 maize, in addition to rapidly being digested in model digestive systems.

3. Allergenicity

There is no one predictive test available that can accurately determine the potential for allergenic cross-reactivity of a protein and therefore a combination of different tests and their holistic analysis thereof. Information that has previously been shown to provide reasonable assurance of non-cross reactivity and which needed to be adduced by the applicant included:

a. Indication of where the donor organism(s) is a known source of allergens in which case there would be a likelihood of allergenicity.
b. Amino acid sequence homology comparison of the newly expressed protein and known allergens.
c. Demonstration of the susceptibility of the newly expressed protein to pepsin digestion.
d. For those proteins that originate from a source known to be allergenic, or have sequence homology with a known allergen, testing in immunological assays it to be performed where sera was available.

The applicant provided information addressing points (a) to (c) and therefore there was no need for (d). It is the considered opinion of the Authority that the evidence provided does not show any potential for the Cry1Ab protein to be allergenic.

4. Nutritional Issues

The applicant needed to demonstrate that MON 810 maize was nutritionally equivalent to conventional maize by conducting comprehensive compositional analysis and also show that the introduction of the modified maize into the food supply does not alter nutrient intake. The compositional analysis included proximate analysis for major components, amino acid, carbohydrate, fatty acid and inorganic analyses, as well as anti-nutrient levels. This data is part of the evidence to demonstrate agronomic, phenotypic and compositional substantial equivalence to preclude any unintended effects.

The applicant provided evidence demonstrating that the MON 810 was compositionally equivalent to conventional maize and there were no biologically significant differences. Variations in values were noted to be within the ranges reported in the literature and therefore considered to be natural variability. The Authority however notes that data on the level of anti-nutritive factors in this case trypsin inhibitors were not provided. The applicant also provided calculation showing very low exposure of Cry 1Ab protein to humans.

The applicant did not provide whole grain feeding data. However, this data is only typically required if there is evidence of biologically significant differences in composition and

nutrition and when there is anticipated difference in consumption patterns compared to conventional counterpart which is not the case there.

Conclusion

It is the Authority's considered opinion and conclusion based on the evidence at hand that the MON 810 maize does not pose any new safety risk compared to conventional maize. It has been demonstrated that it is substantially equivalent compositionally and nutritionally to conventional maize and the intended use of the modified maize in Kenya is similar to conventional maize. The protein tests and bioinformatics analysis indicate that the newly expressed protein, Cry1Ab, is not toxic and no significant similarity to known allergens was found. Additionally, Cry 1Ab protein has been shown to be rapidly degraded in model digestive systems. History of safe use of the donor and recipient organisms is further evidence of the safety MON 810.

It is also important to note that MON 810 maize has been evaluated in other jurisdictions and results of which are available publicly. The modified maize is commercially available in many countries and has received regulatory approval for import since 1996 with no report of adverse health effect to humans.

Signed:_____ **Dated:** 19 December 2016

WILLY K. TONUI, PhD, RBP, EBS
CHIEF EXECUTIVE OFFICER
NATIONAL BIOSAFETY AUTHORITY