DECISION AND **SUMMARY OF FOOD SAFETY ASSESSMENT FOR Bt176**

A) Description of the recombinant-DNA plant;

Common name : Maize
Family name : Gramineae
Genus *: Zea*
Species *: mays*
Common : Maize or Corn

B) **Description of the host plant** and its use as food;

The host plant is called ***Zea mays***, Maize and corn refer to *Z. mays ssp. mays*. However, other subspecies of *Zea mays* are referred to as Teosintes. Maize is an annual grass that grows up to 4m tall. The female inflorescences, ears develop in leaf axils on the stalk, which terminates in the male inflorescence, the tassel. Maize has broad leaf sheaths that overlap around the stalk and leaves arranged in two opposing rows along the stalk.
It is the world's leading cereal after rice and wheat and is not considered a pest anywhere in the world.

C) **Description of the donor organism**(s);

The genes used in the construction of the genetically-modified maize were obtained from the following bacterial species:*Bacillus thuringensis Streptomyces hygroscopicus and Escherichia coli.* .

D) **Description of the gene modification**(s);

The genetically-modified maize with the transformation event BT 176 was created by insertion of two copies of a truncated synthetic versions of the full length of the gene coding for the crystal 1Ab proteins (*cry1Ab)* from *Bacillus thuringiensis subsp. Kurstaki*. The synthetic truncated *cry1Ab* gene encodes a protein that corresponds to the first 648 amino acid of the N-terminal fragment of the 1155 amino acid full length native *Cry 1Ab* protein. It includes the portion of the native protein tnecessary for insect control. The following are the summary details on the introduced genetic elements:

- Event Bt176 that produces truncated C*ry1Ab*protein for control of certain lepidopteran pests.
- Phosphinothricin-*N*-acetyltransferase gene (also known as the bar gene) obtained from*Streptomyces hygroscopicus*-STRHY, conferring resistance to the herbicide, glufosinate.
- Beta lactamase gene (also known as the bla gene) from *Escherichia coli*- used as a selectable marker and conferring resistance to ampicilin
- CaMV 35S promoter-Cauliflower mosaic virus

- CaMV 35S terminator –Cauliflower mosaic virus
- Phosphoenolpyruvate carboxylase gene promoter from maize
- Calcium-dependant protein kinase (CDPK) promoter from maize.
- Phosphoenolpyruvate carboxylase intron 9 from maize.

The expression of the two copies of the cry 1Ab genes are under either the control of a pollen-specific promoter from the calcium dependent protein kinase or the green tissue specific promoter of the phosphoenolpyruvate carboxylase gene. Both promoters were isolated from maize while termination sequences were from cauliflower mosaic virus (CaMV).

The bar gene from *Streptomyces hygroscopicus* which encodes for phosphinotricin acetyltransferase (PAT) gene confers resistance to glufosinate herbicides. Its expression was under the regulation of the 35S CaMV promoter.

The *bla* gene from *E. coli* is not expressed in plant cells but is used as a selectable marker for screening bacterial colonies for the presence of the plasmid vector.

The plasmids used as vectors for the transformation of BT 176 maize were pCIB3064 and pCIB4431

The biolistic method was used for the transformation of maize plant cells..

E) Characterization of the genetic modification(s);

a) Quantitative PCR was used for detection of maize event Bt176 (verified by the EU-RL GMFF in the context of Commission Decision 2007/304/EC)
b) Qualitative PCR was used for detection of the junction between the CDPK promoter from maize and the synthetic cry1Ab gene (ISO/FDIS 21569:2005).
c) Quantitative PCR was used for detection of the junction between the synthetic cry1Ab gene and the phosphoenol-pyruvate carboxylase intron N.9.

F) Safety assessment:

a) Expressed substances (non-nucleic acid substances);

Toxicity and allerginicity analysis: Results from risk analysis studies revealed no known adverse effects in extensive animal studies. Data on the potential toxicity and allergenicity of the proteins encoded by the transferred genes as well as potential changes to naturally occurring toxins or anti-nutrients have been reviewed and no toxicity has been reported in maize. Corn has no endogenous toxins or anti-nutrients. Results from studies, including acute oral toxicity tests and model digestion system studies, indicate that the new proteins expressed in Bt-176 corn are non-toxic and unlikely to have allergenic effects. No protein product from the antibiotic resistance *bla* gene is expected in the genetically modified corn, as the gene has bacterial-specific regulatory elements. From these data, it can be concluded that the food products derived from insect-protected Bt-176 corn should pose threat to animals or humans. Such maize is not deemed to be a source of any toxin or allergen and its biochemical composition is equivalent to that of maize produced by conventional breeding methods..

b)Compositional analyses of key components;

Likelihood of adverse effects being realized is considered low because:

- Bt176maize was found not to have any hazards when compared to maize produced through single event gene transfer or through conventional breeding. Gene modification using the stacked gene events were not found to cause any compositional changes and the maize was found to have no risk when used as food, feed or processing and commercial release.
- Results also found that dispersal and survival characteristics of the genetically modified maize have not changed in comparison to the conventional counterpart. Maize dissemination can only be accomplished by seed dispersal which does not occur naturally.
- Invasiveness and persistence of the genetically modified maize and in the environment has never been observed when compared to the conventional counterpart. Bt176maize was also found to be agronomically comparable to the conventional maize. Results from compositional analyses demonstrated no significant differences between Bt-176 corn kernels and its conventional counterparts supporting the view that Bt-176 corn kernels are compositionally and nutritionally equivalent to conventionally produced corn.

c) **Evaluation of metabolites;**

These were found to be similar to from conventional maize. Therefore, a comprehensive evaluation of Bt176 maize and controls showed no biologically meaningful differences for grain and forage compositions including major nutrients.

d) **Food processing;**

This was found to be similar to that of the conventional counterpart and no alterations were observed in heat treatment studies when compared to conventional maize.

e) **Nutritional modification**;

No new or novel metabolites were observed in the genetically modified maize and it wasfound to have metabolites similar to those from conventional counterpart. G) **Other considerations**

In assessing all of the above data, SAC has concluded that food derived from insect protected Bt-176 corn has the same composition as that derived from maize produced by conventional breeding methods. No toxins, allergens or constinuents were found in the transformed maize and the maize is deemed to be substantially equivalent to that produced by conventional methods of plabt breeding.

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H)**Public Consultation/Comments**;

Upon receipt of the application and callfor public comment on 21st May, 2018. Only one submission was received. An attachment of the submission is provided entitled ''Essential Commodities''.

Decision:

Permit Awarded