SUMMARY OF FOOD SAFETY ASSESSMENT FOR MIR 162

A) Description of the recombinant-DNA plant;

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

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

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

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

Donor organism used to develop MIR162 was *Bacillus thuringensis (Bt), Naturally occurring soil* borne bacterium that produces crystal- like proteins ('Cry' proteins). Cry proteins binds to specific receptors.

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

MIR162 was developed through *Agrobacterium tumefaciens* (also known as *Rhizobium radiobacter*) mediated transformation of immature embryos derived from a proprietary maize line using the pNOV1300 plasmid and *A.tumefaciens* strain

i. The *vip3Aa19* gene Cassette
This is a synthetic, maize-optimized, *vip3Aa1* gene derived from *B. thuringiensis* strain AB88. The *vip3Aa19* protein differs from the Vip3Aa1 protein by a single amino acid at position 284 (L284Q). The *vip3Aa19* gene is under the control of the maize polyubiquitin promoter and the intron #9 from the maize phosphoenolpyruvate carboxylase gene. The transcription is terminated by the 35S terminator from the Cauliflower mosaic virus (CaMV).

ii. *pmi* gene cassette (used as selectable marker)
The pmi gene is derived from *Escherichia coli* and encodes phosphomannose isomerase (PMI) enzyme. The gene is under the control of the maize polyubiquitin promoter and the transcription is terminated by the nopaline synthase (NOS) terminator from *A. tumefaciens*. Expression of PMI enables transformed maize cells to utilise mannose and therefore to survive on media in which mannose is the sole source of carbon.

E) **Characterization of the genetic modification(s);**

Southern blot analysis shows that MIR162 contains a single insert, single copies of the *vip3Aa19* and *pmi* genes two copies of the polyubiquitin promoter corresponding to the two copies of the promoter present in plasmid pNOV1300 used for the transformation, one copy of the NOS terminator and none of the backbone sequences from pNOV1300.

According to EFSA in the Scientific opinion on insect-resistant GM maize shows that analysis of the insert and integration site, including flanking sequences and bioinformatic analysis, have been performed to characterise the transformation event MIR162, and this do not raise safety concerns. The levels of the Vip3Aa20 and PMI proteins were analysed sufficiently and the stability of the genetic modification demonstrated over several generations.

F) **Safety assessment**:

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

- **Toxicity and Allerginicty:** There are no known adverse effects detected based on extensive characterization and Bioinformatics analysis on the allergen database.There were no hits with known toxins. The search for putative allergens showed no alignments with the FARRP allergen database that exceeded the minimum 35 % shared identity over a minimum of 80 amino acids for the BLASTX alignment. Therefore Blast analysis revealed no similarities to known toxins or allergens. The proteins Vip3Aa20 and PMI expressed in maize MIR162 have been assessed and show no safety concerns for humans, animals and the environment. While cauliflower mosaic virus (CaMV) in the promoter and terminator for the pat gene also do not cause disease symptoms in plants nor encode for infectious agents.

b) Compositional analyses of key components;

Likelihood of adverse effects being realized is considered low because:

- Hazards associated with MIR162 are no greater than those associated with conventional maize-So hazard characterization cannot change as a result of containing Cry genes as food, feed or processing and commercial release. The comparators were conventional counterpart maize lines with genetic similarity considered acceptable to MIR162 maize. Documents on key compositional parameters show that they were within background ranges.
- Dispersal and survival characteristics have not changed in comparison to the conventional counterpart.
- Invasiveness of natural environments and persistence in the environment has not changed in comparison to the conventional counterpart. MIR162 was agronomical comparable to the conventional maize and its composition falls within the range of non-commercial GM varieties, except for expression of the Vip3Aa20 and PMI proteins.

c) **Evaluation of metabolites;**

These are the same as the conventional counterpart. Therefore, a comprehensive evaluation of MIR162 maize and controls showed no biologically meaningful differences for grain and forage compositions either for major nutrients (EFSA, 2010 Scientific opinion on insect-resistant GM maize MIR162 for feed and food uses, import and processing).

d) **Food processing;**
Same as the conventional counterpart. No alterations with heat- Stable
e) **Nutritional modification**;
Metabolites in the modification are not shown as there are the same as the conventional counterpart so no recommendations other than procedures that might apply to the conventional maize.
G) **Other considerations**
None

In conclusion the objective of each safety assessment is to provide a guarantee, in the light of the best available scientific knowledge, that the food does not cause harm to animal or human health and the biodiversity when prepared, used and/or eaten according to its intended use. The expected endpoint of such an assessment will be a conclusion regarding whether the new food is as safe as the conventional counterpart taking into account dietary impact of any changes in nutritional content or value. In principle, therefore, the result of the safety assessment process is to define the product under consideration in such a way as to enable risk managers to determine whether any measures are needed and if so to make well-informed and appropriate decisions.

Public Consultation/Comments;
Nothing has been received so far after the advert was placed in the media-National and Daily mail.