

PnP APPLICATION

SUMMARY OF FOOD SAFETY ASSESSMENT

A) Description of the recombinant-DNA plant;

Common name: Maize,
Family name : Poaceae
Genus : *Zea*
Species : *Zea mays* L.
Sub Species : *mays*
Common : Maize or corn

PnP has provided the information

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

Zea mays, reproduces sexually through the production of seed. Both self and cross fertilization are usually possible. Pollen dispersal is limited by many factors such as size, rapid settling rate and survivability. Greater than 98% of most pollen settles within a maximum distance of 25 to 50 meters from its source (EEA, 2002; Jarosz *et al*, 2005; Devos *et al.*, 2005) 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. Fertilization is affected by a number of complicating factors like genetic sterility factors and differential growth rates of pollen.

The potential of genetic transfer and exchange of with other organisms is limited to other maize plants as there are no wild relatives. Hence maize is not considered a pest anywhere in the world.

Maize is an annual crop and seeds are the only survival structures. They cannot be dispersed without mechanical disruption of cobs and show little or no dormancy. No natural regeneration is known.

Maize is the world's leading cereal after rice and wheat.

C) Description of the donor organism(s);

Donor organism used to develop GA21 was *Agrobacterium tumefaciens*, strain CP4 are common soil bacteria. The organism is ubiquitous in nature.

D) Description of the genetic modification(s);

GA21 was genetically modified to produce the mEPSPS. The genetic modification involved a single insert and no vector sequence exists elsewhere in the plant genome. The modification allows production of proteins mEPSPS to enhance the tolerance of maize to herbicide products containing glyphosate.

E) Characterization of the genetic modification(s);

Molecular analysis showed that the genetic modification contained a single insert and that no vector sequence exists elsewhere the plant genome.

F) Safety assessment:

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

Toxicity: mEPSPS is unlikely to be toxic to humans. No known adverse effects detected when it was feed to mice.

Allergenicity: It has no significant sequence identity to known allergens and it is not stable in simulated gastric fluid

b) Compositional analyses of key components;

Likelihood of adverse effects being realized is considered low because:

- Studies comparing the composition, shows that GA21 is substantially equivalent to the conventional maize.
- No adverse effects on the environment and humans
- 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. No environmental effects through interactions with non-target or organism.

Therefore, GA21 has no meaningful potential to disperse, persist without human intervention or invade non agricultural areas.

c) Evaluation of metabolites;

These are the same as the conventional counterpart apart from expression of mEPSPS. Therefore, GA21 maize expresses a mutated maize EPSPS enzyme (mEPSPS).

d) Food processing;

Same as the conventional counterpart. No alterations with heat- Stable

e) Nutritional modification; and

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

No biologically significant unintended changes in seed dispersal or other traits that might affect the ability of maize to survive without human intervention have been seen on agronomic trials in South Africa or elsewhere.

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

N/B No summary on BT Maize cause this was done in the previous assessments